Flu Immunisation Programme 2018/19 Northern Ireland

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This training resource has been designed to educate healthcare practitioners involved in delivering the flu immunisation programme for the 2018/19 flu season. This resource does **not** cover the actual administration techniques involved in vaccination, and it intended as **an update for staff who have completed core immunisation training already.** If staff are required to deliver vaccinations they should refer to their line manager for additional training that may be required.

Influenza / Flu Overview

- Is an acute viral infection of the respiratory tract
- Is highly infectious & spreads rapidly in closed communities
- Can be spread by people with mild / no symptoms
- Usually occurs most often in an 8-10 week period during the winter

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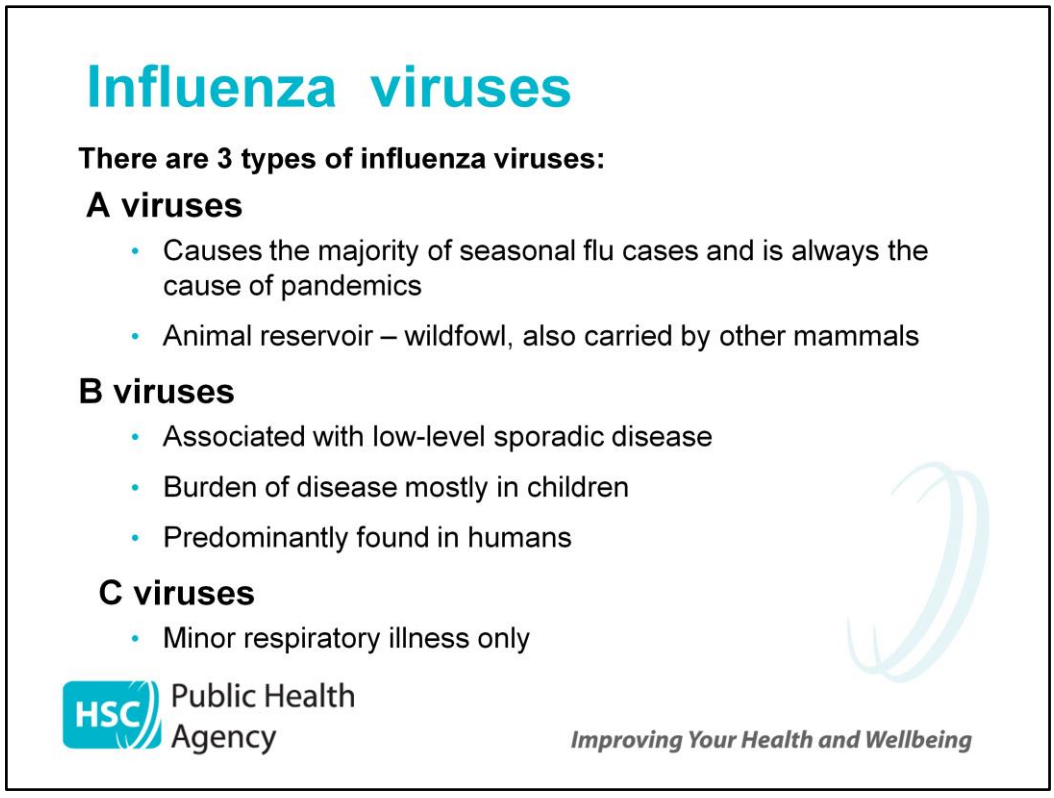
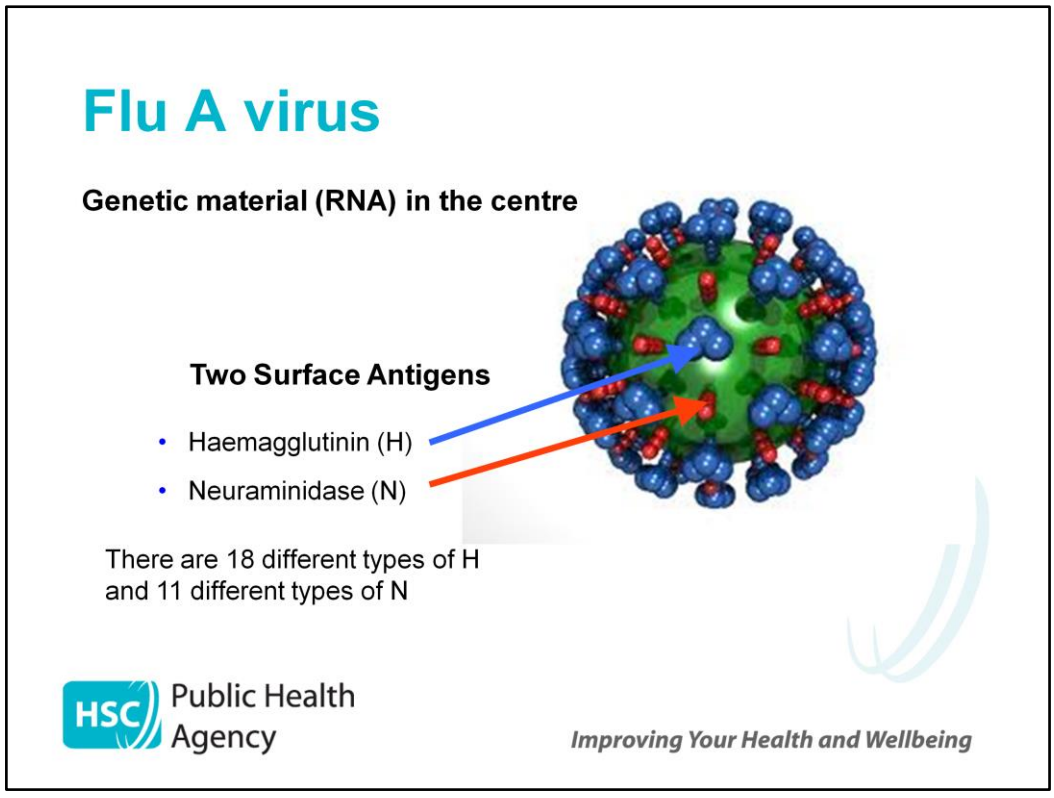
Influenza virus causes an acute viral infection of the respiratory tract commonly referred to as flu.
Flu is highly infectious and spreads rapidly in closed communities. It is possible to have been infected with flu and to have mild / no symptoms. Asymptomatic people can still transmit flu to other people. Most cases of flu occur during an 8-10 week period during the winter months but sometimes the flu season can start earlier. It is important that people are vaccinated by the end of December to prevent infection.



There are three types of influenza virus: A,B & C. Influenza A & B are responsible for most clinical illness. Influenza A causes the majority of seasonal flu cases and is the cause of Pandemics. The virus is found in many different animals and may spread between them. Birds, particularly wildfowl are the main animal reservoir.

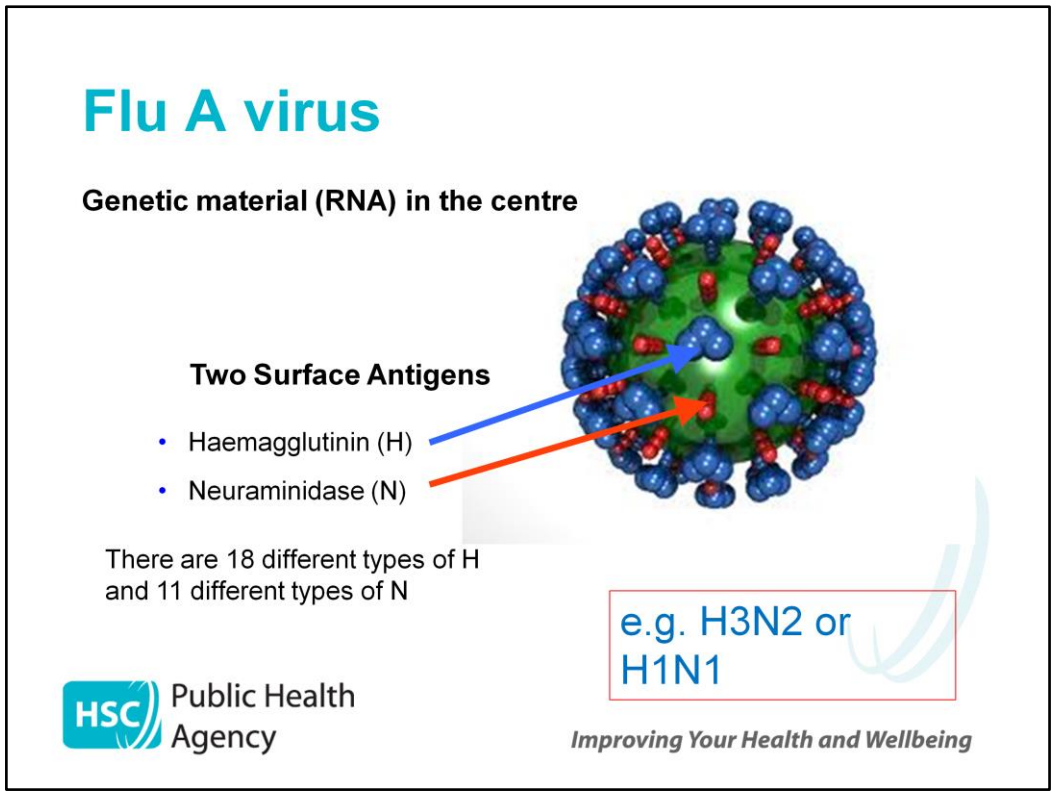
Influenza B tends to cause less severe disease and smaller outbreaks. It is predominantly found in humans and the burden of disease is mostly in children. Influenza C causes minor respiratory Illness only.



This slide shows a schematic model of an influenza A virus. Influenza A is an RNA Virus and there are two antigens on the surface of the virus as illustrated.

The role of the Hemagglutinin (H) antigen is to bind to the cells of the host. There are currently 18 known different types Of H surface antigen.

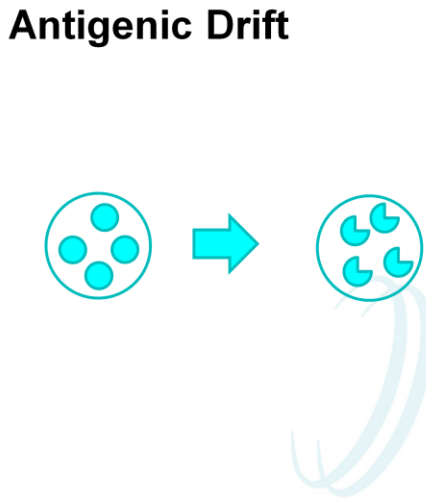
The role of the Neuraminidase (N) antigen is to release the virus from the host cell surface. There are currently 11 known different types of N surface antigen.



The different types of H and N antigens are identified by numbers that when combined provide the name of the influenza A virus e.g. H3N2 / H1N1.

Antigenic Drift

minor changes (natural mutations) in the genes of flu viruses that occur gradually over time



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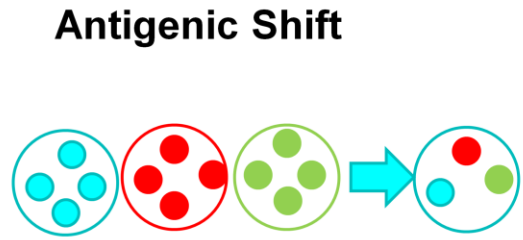
Influenza A viruses are prone to antigenic variation.
Minor changes that occur as a result of natural mutations that occur gradually over time are referred to as **antigenic drift**.

Antigenic Shift

Two or more different strains combine. This abrupt major change results in a new subtype. Immunity from previous flu infections/vaccinations may not protect against the new subtype, potentially leading to a widespread epidemic or pandemic



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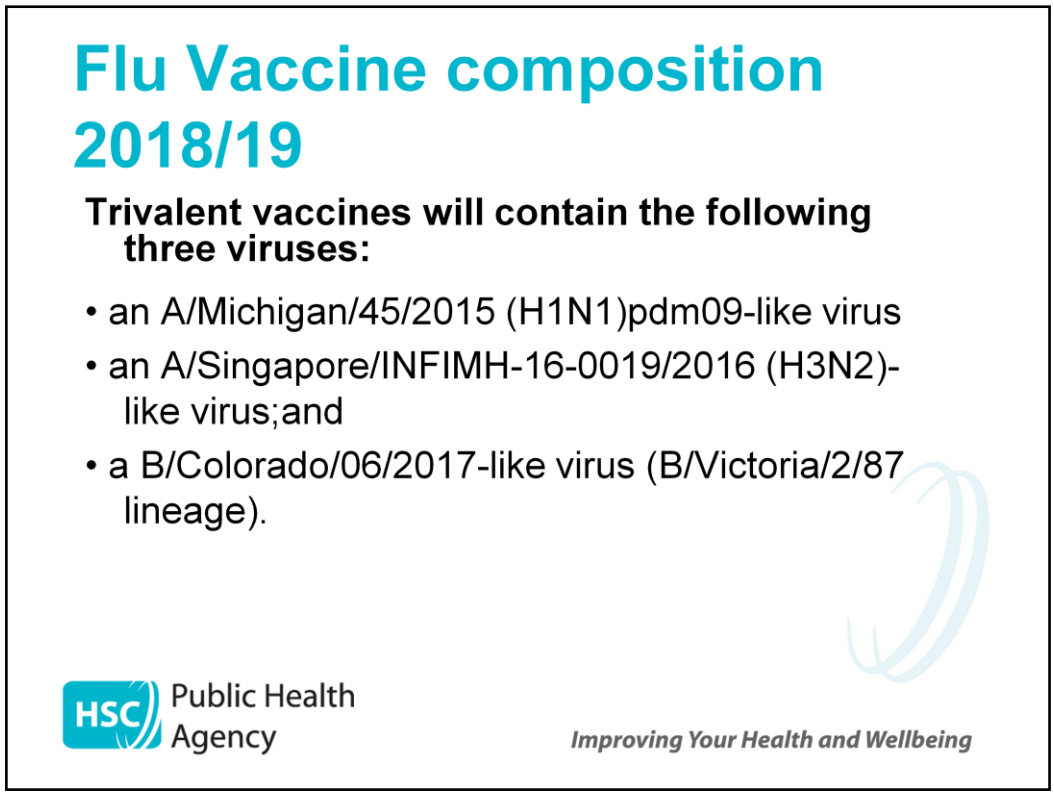
Influenza A virus can also change abruptly when 2 / more different strains of influenza A combine, resulting in antigenic shift and a new subtype of influenza A, to which little / no immunity exists within the general population.

The World Health Organization (WHO) convenes a group that reviews the global influenza situation (once each year for the northern hemisphere and once for the southern hemisphere) and recommends which flu strains should go in the seasonal vaccine to be produced by manufacturers for the following season six to eight months later. This recommendation is based on information about the circulating viruses and epidemiological data from around the world at that time.

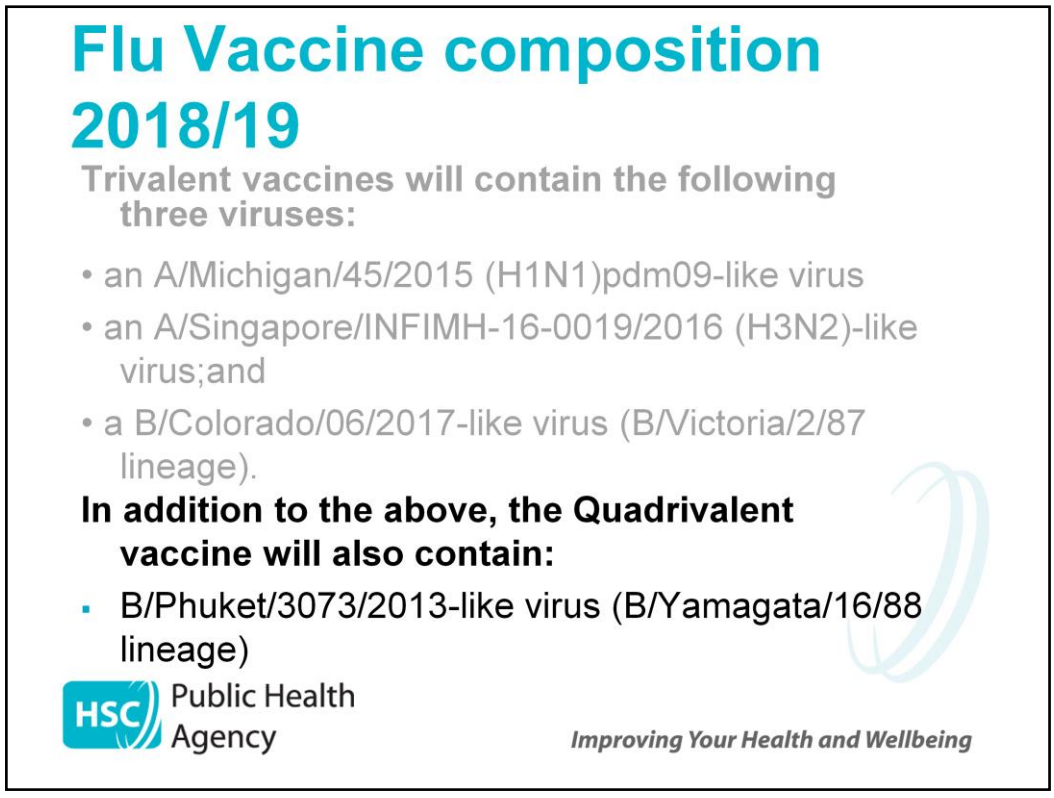
Trivalent vaccines e.g. FLUAD contain two subtypes of influenza A and one B virus.

Quadrivalent vaccines (for example Fluenz tetra intranasal vaccine/ the Sanofi Pasteur Quadrivalent Inactivated vaccine offer additional protection against a second strain of influenza B. The use of quadrivalent flu vaccines is expected to improve the matching of the vaccine to the circulating B strain(s).



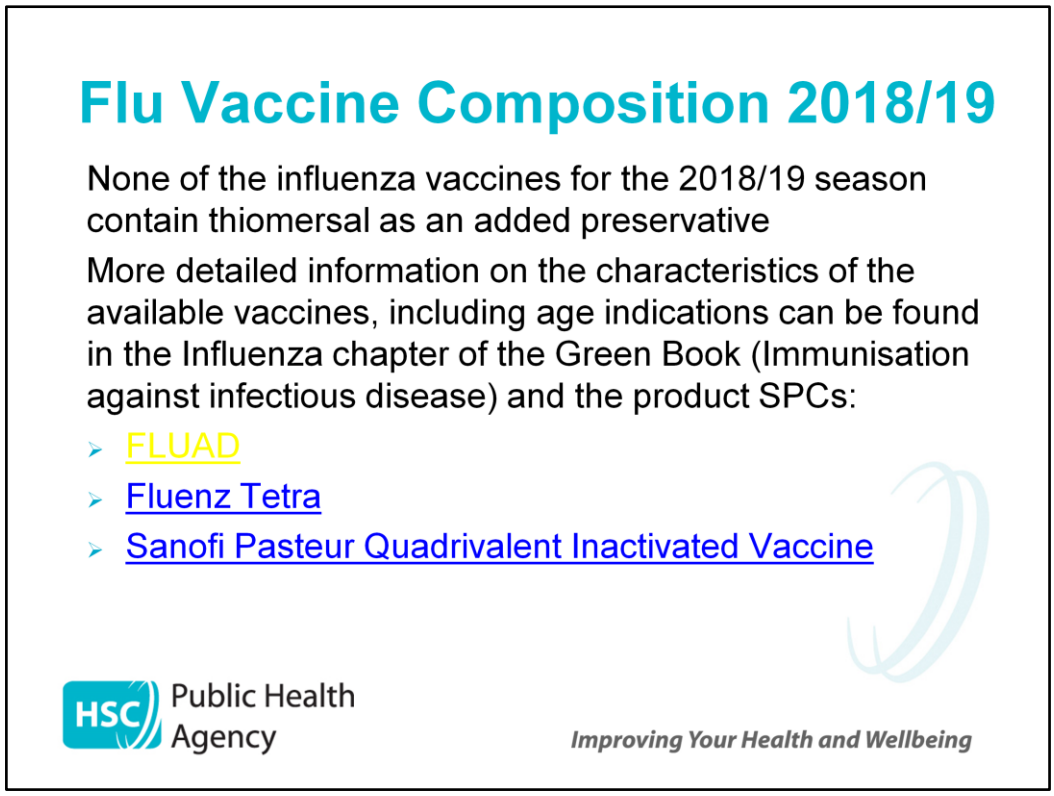
The WHO has recommended that this year's trivalent seasonal flu vaccine contains the following three viruses:

- an A/Michigan/45/2015 (H1N1)pdm09-like virus
- an A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus;and
- a B/Colorado/06/2017-like virus (B/Victoria/2/87 lineage).



and that the Quadrivalent vaccine contains an Antigen for an additional B strain.

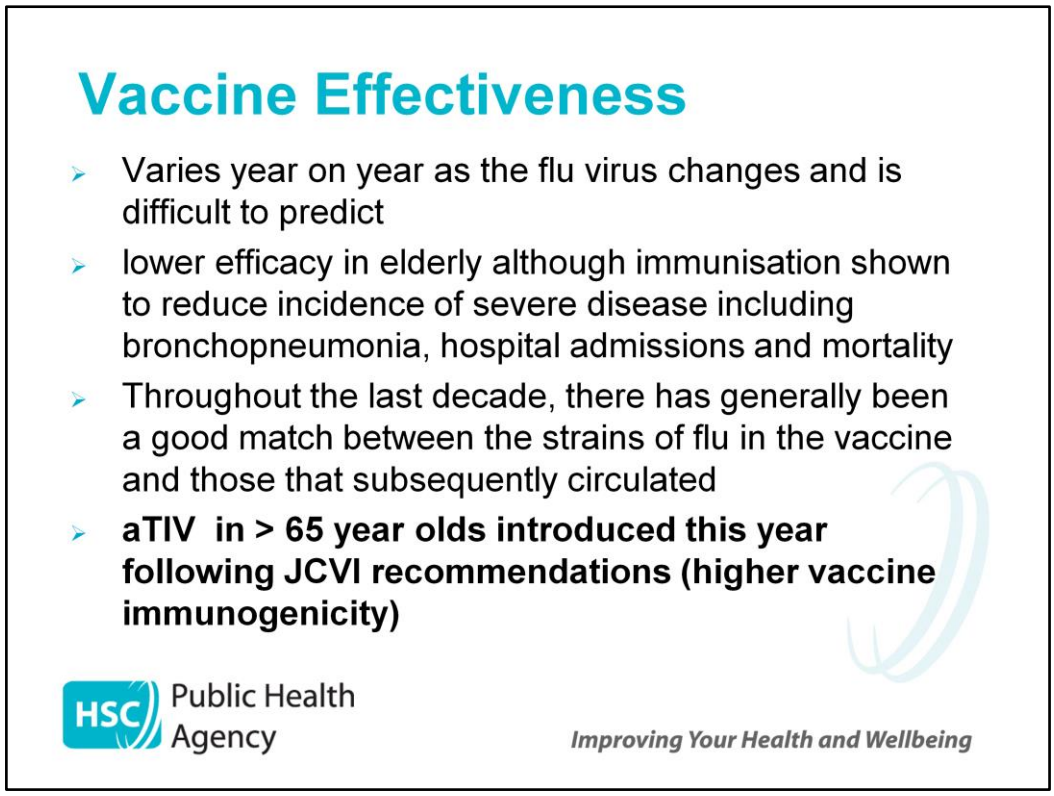
- B/Phuket/3073/2013-like virus (B/Yamagata/16/88 lineage)



None of the influenza vaccines for the 2018/19 season contain any preservatives such as
thiomersal.

Detailed information about the composition of the flu vaccines can be found in the SPC for that particular vaccine by clicking on the hyperlinks provided:

- FLUAD
https://www.medicines.org.uk/emc/product/9223/smpc
- Sanofi Pasteur Quadrivalent Inactivated Vaccine
https://www.medicines.org.uk/emc/product/666
- Fluenz Tetra
https://www.medicines.org.uk/emc/product/3296

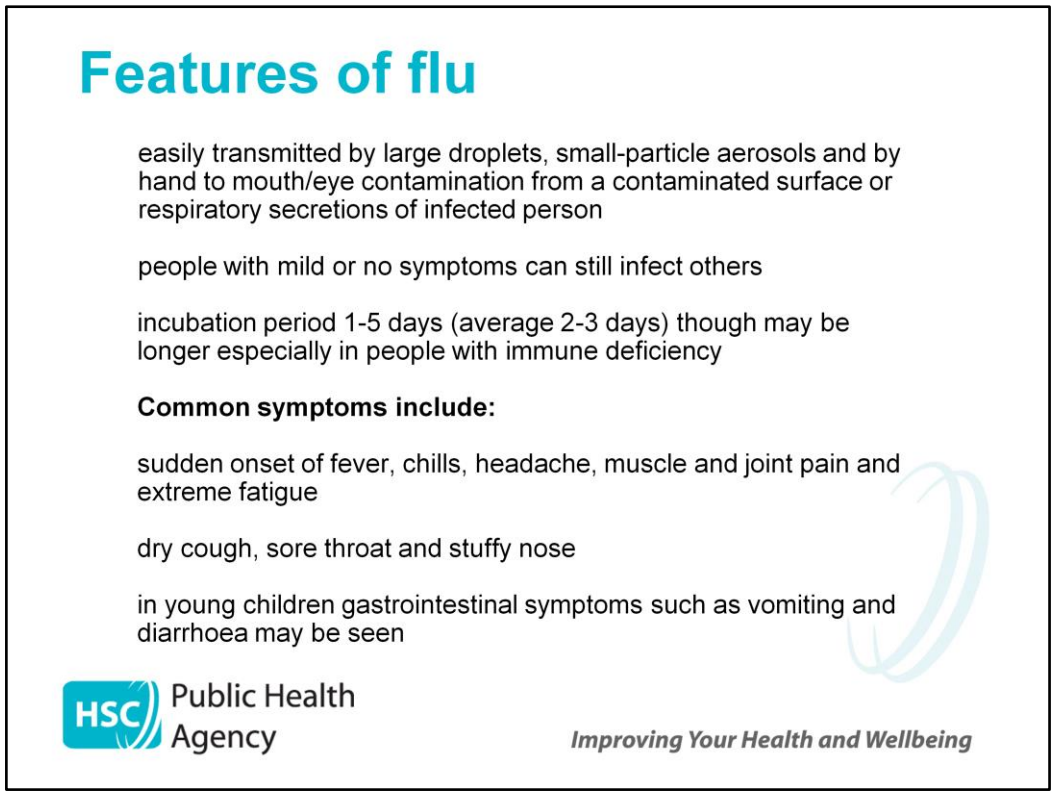


The PHE published data on the effectiveness of the flu vaccine in the 2017/18 Season on 18th July 2018:
https://www.gov.uk/government/news/flu-vaccine-effectiveness-in-2017-to-2018-season

Vaccine effectiveness varies year on year as the flu virus changes and is difficult to predict. Last year's flu vaccine provided good protection against a(H1N1)pdm09 and good protection for the Quadrivalent vaccine in children against the main flu B strain which circulated last season. The flu vaccine has a lower efficacy in elderly although immunisation is shown to reduce the incidence of severe disease including Bronchopneumonia, hospital admissions and mortality.

Generally speaking throughout the last decade there has generally been a good match between the strains of flu in the vaccine and those that subsequently circulated.

This upcoming season we are recommending that all those under 65 have the Quadrivalent vaccine which protects against both the main B strains and the 2 main flu A subtypes. We are also making a new vaccine available for all adults aged 65 or over to improve the immune response.



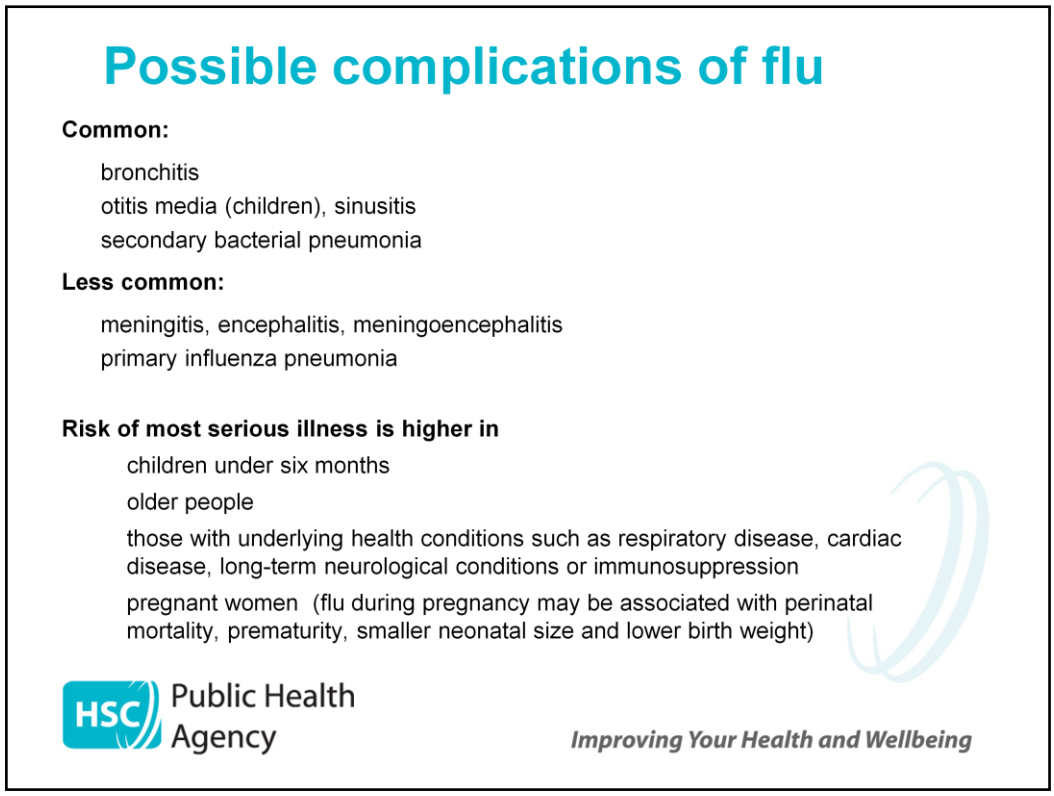
Flu is easily transmitted by large droplets, small particle aerosols and by hand to mouth/eye contamination from a contaminated surface or respiratory secretions of an infected person.

Serological studies in healthcare professionals have shown that approximately 30 to 50% of influenza infections can be asymptomatic but the proportion of influenza infections that are asymptomatic may vary depending on the characteristics of the influenza strain.

The average incubation period is 2-3 days but may be longer in individuals who are immunocompromised.

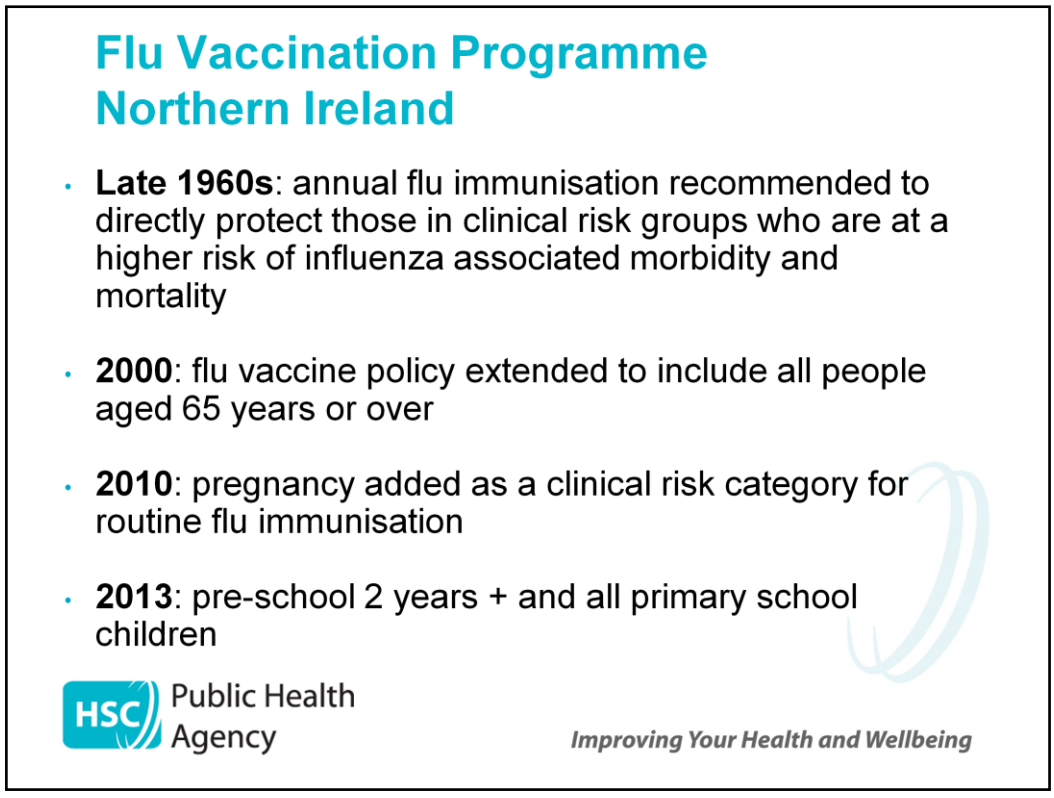
Common symptoms include onset of fever, chills, headache ,muscle and joint pain and extreme fatigue. Symptoms may also include a dry cough, sore throat and stuffy nose. Young children may also experience gastrointestinal symptoms such as vomiting and diarrhoea.

In healthy individuals, flu is usually unpleasant but self-limiting with recovery within 2-7 days.

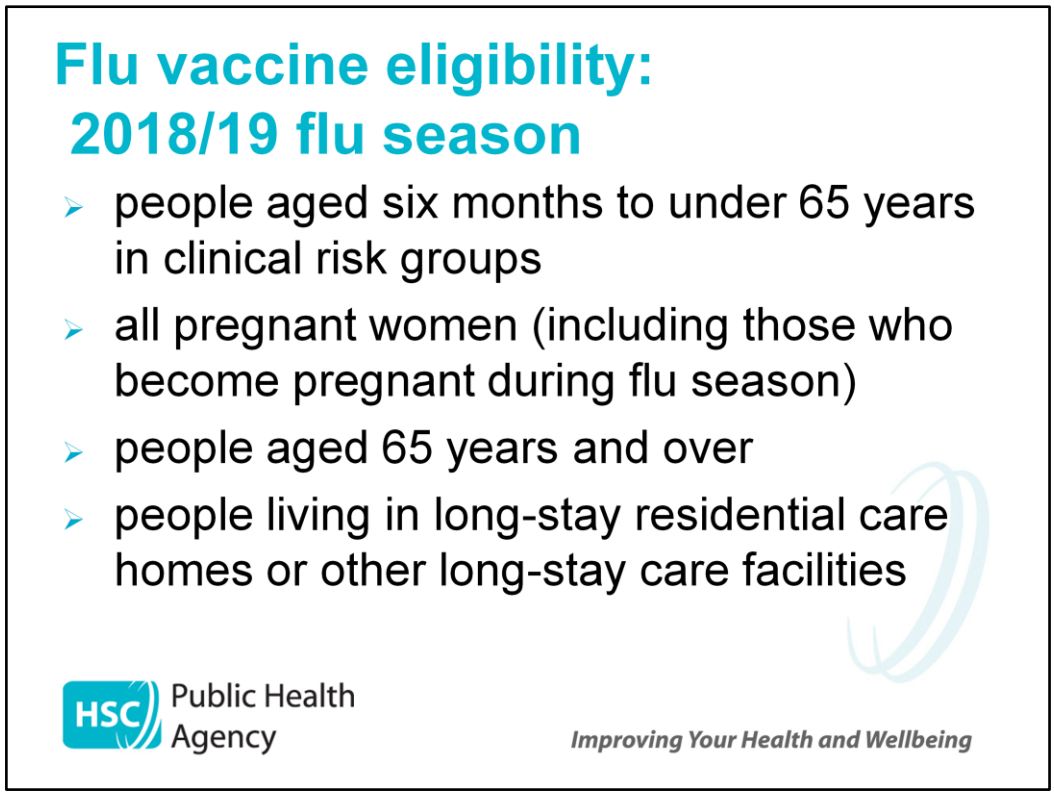


Common complications of flu include bronchitis, otitis media in children, Sinusitis and secondary bacterial pneumonia. Less commonly flu causes Meningitis, encephalitis, meningoencephalitis and primary influenza Pneumonia. The risk of serious illness from flu is higher among children under six months of age, older people and those with underlying health conditions such as respiratory disease, cardiac disease or immunosuppression, as well as pregnant women.

These groups are at greater risk of complications from flu such as bronchitis or pneumonia. Flu in pregnancy is also associated with perinatal mortality, prematurity, smaller neonatal size and lower birth weight.



The flu vaccination programme was introduced into NI in the late 1960s and was recommended for those in clinical risk groups that have a higher risk of associated morbidity and mortality. In 2000 the programme was extended to Include everyone > 65 years of age. In 2010 pregnancy was added as a Clinical risk category for routine flu immunisation and in 2013 the programme Was extended to include pre-school children from 2 years and older and all Primary school children.



The flu programme for this year remains unchanged and includes:

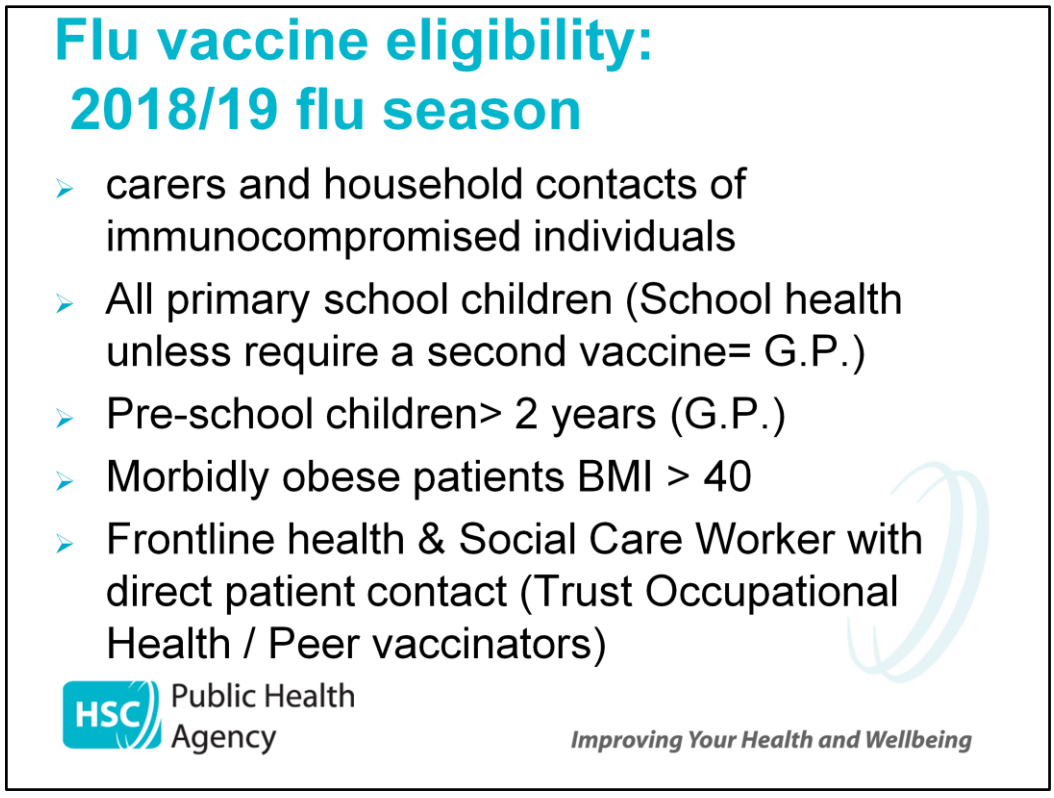
•people aged six months to under 65 years in clinical risk groups

•all pregnant women (including those who become pregnant during flu season)

•people aged 65 years and over

- people living in long-stay residential care homes or other long-stay care facilities

(Long stay care facilities" does not include prisons, young offender institutions, or university halls of residence)



It also includes:
•carers and household contacts of immunocompromised individuals
("Carers" are those who are in receipt of a carer's allowance, or those who are the main carer of an older or disabled person whose welfare may be at risk if the carer falls ill
•All primary school children (School health unless require a second vaccine= G.P.)
•Pre-school children> 2 years (G.P.)
•Morbidly obese patients BMI > 40

Consideration should also be given to the vaccination of household contacts of immunocompromised individuals, specifically individuals who expect to share living accommodation on most days over the winter and for whom close contact is unavoidable.

This list is not exhaustive, and the healthcare practitioner should apply clinical judgement to take into account the risk of flu exacerbating any underlying disease that a patient may have, as well as the risk of serious illness from flu itself. Flu vaccine should be offered in such cases even if the individual is not in the clinical risk groups specified above.

It is also extremely important for frontline health and social care workers with Direct patient / service user contact to receive their flu vaccine. This includes staff In all health and social care trusts, general practices, care homes and domiciliary care.

Clinical risk groups who should receive flu vaccine (1)

Clinical risk category	Examples (this list is not exhaustive and decisions should be based on clinical judgement)
Chronic respiratory disease	Asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission. Chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Children who have previously been admitted to hospital for lower respiratory tract disease. see precautions section on live attenuated influenza vaccine
Chronic heart disease	Congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease.
Chronic kidney disease	Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation.
Chronic liver disease	Cirrhosis, biliary atresia, chronic hepatitis
Chronic neurological disease (included in the DES directions for Wales)	Stroke, transient ischaemic attack (TIA). Conditions in which respiratory function may be compromised due to neurological disease (eg polio syndrome sufferers). Clinicians should offer immunisation, based on individual assessment, to clinically vulnerable individuals including those with cerebral palsy, learning difficulties, multiple sclerosis and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological disability
Diabetes	Type 1 diabetes, type 2 diabetes requiring insulin or oral hypoglycaemic drugs, diet controlled diabetes.

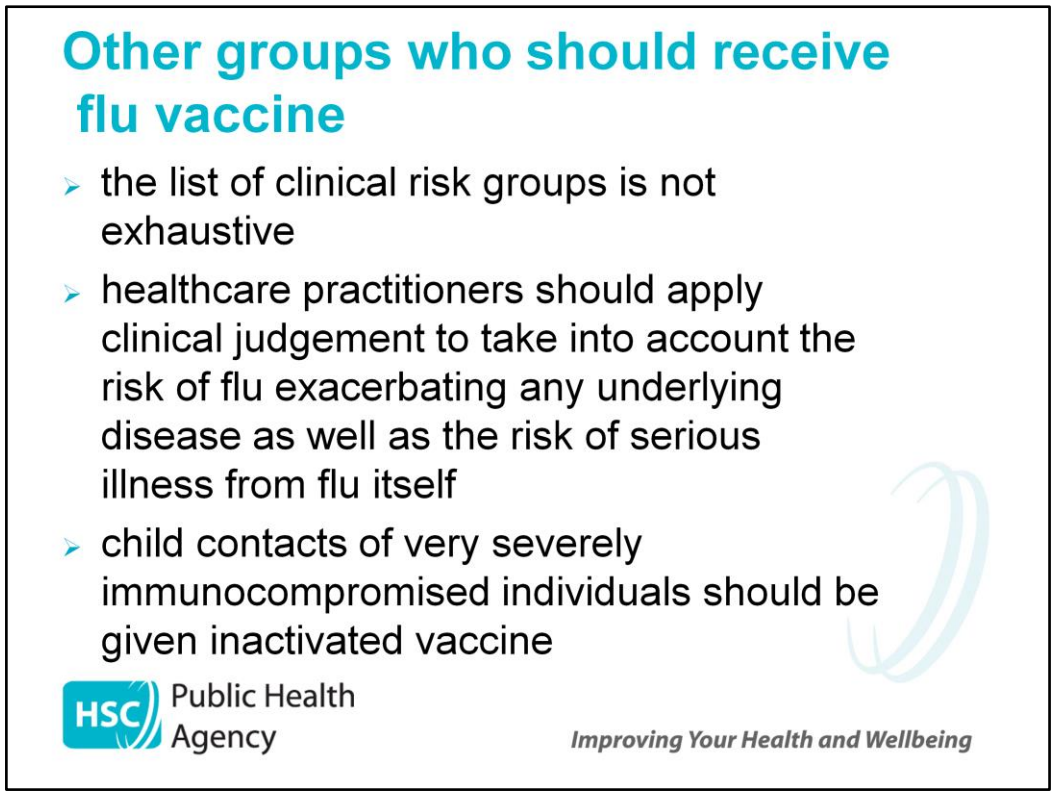
Flu vaccine should be offered to the eligible clinical risk groups set out in this table taken from The flu chapter of the green book.

You are not expected to be able to read the detail on the tables on these two Slides but should know that clinical risk groups include those with chronic Respiratory, heart, kidney, liver and neurological disease. Clinical risk groups also Include those with diabetes,

Clinical risk groups who should receive flu vaccine (2)

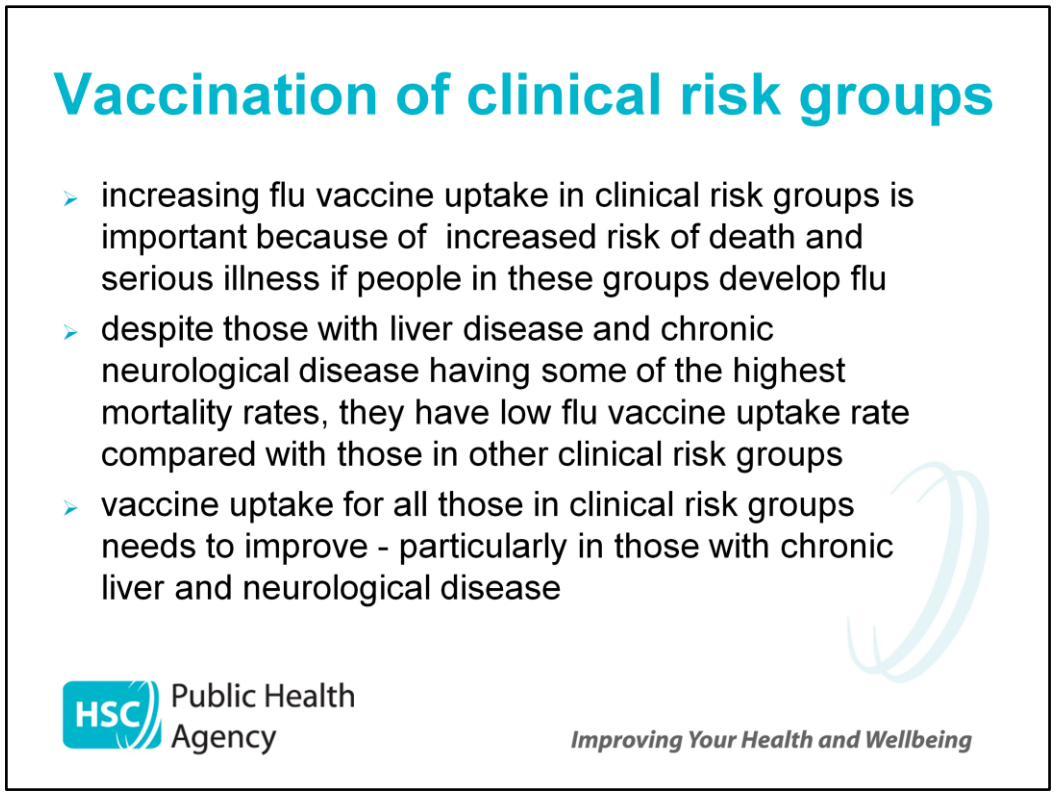
Clinical risk category	Examples (this list is not exhaustive and decisions should be based on clinical judgement)
Immunosuppression (see contraindications and precautions section on live attenuated influenza vaccine)	Immunosuppression due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, bone marrow transplant, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (eg IRAK-4, NEMO, complement disorders) Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day (any age), or for children under 20kg, a dose of 1mg or more per kg per day. It is difficult to define at what level of immunosuppression a patient could be considered to be at a greater risk of the serious consequences of influenza and should be offered influenza vaccination. This decision is best made on an individual basis and left to the patient's clinician. Some immunocompromised patients may have a suboptimal immunological response to the vaccine.
Asplenia or dysfunction of the spleen	This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction.
Pregnant women	Pregnant women at any stage of pregnancy (first, second or third trimesters). (see precautions section on live attenuated influenza vaccine)

People with immunosuppression, asplenia / dysfunction of the spleen and pregnant women. More details and examples are provided in the flu chapter of the Green Book but note that this list is not exhaustive and decisions should be based on clinical judgement.

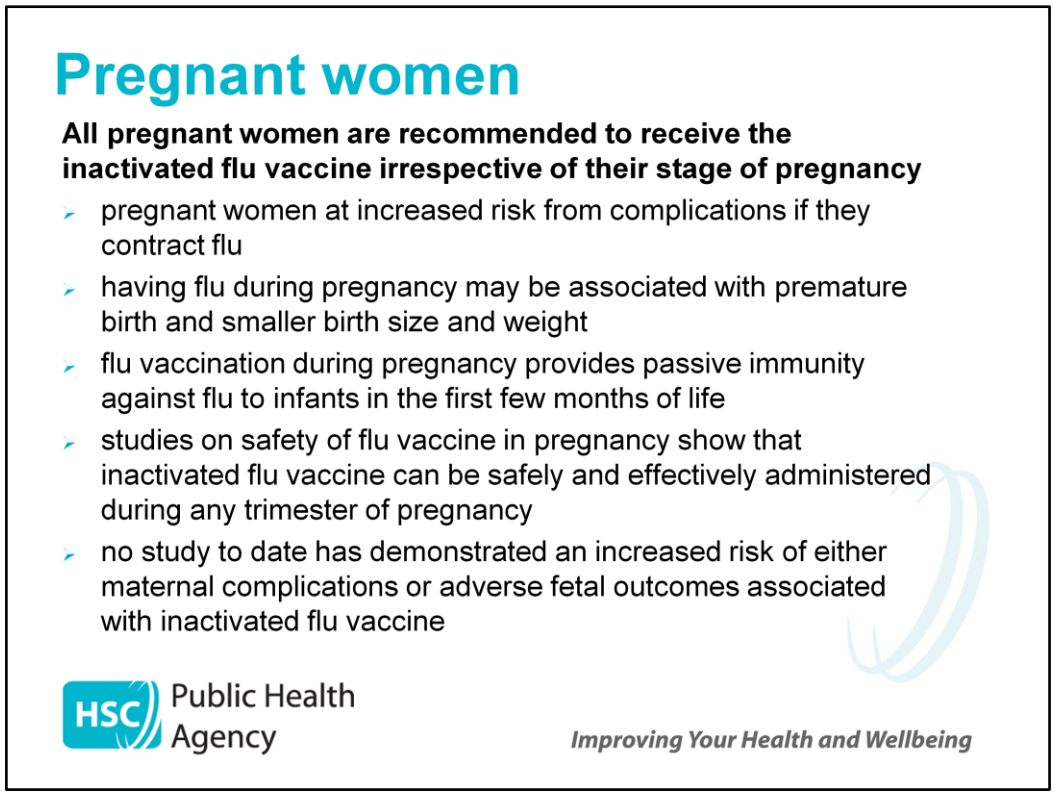


As already mentioned, the list of clinical risk groups is not exhaustive, and the healthcare practitioner should apply clinical judgement to take into account the risk of influenza exacerbating any underlying disease that a patient may have, as well as the risk of serious illness from flu itself. Flu vaccine should be offered in such cases even if the individual is not in one of the specified clinical risk groups.

Consideration should also be given to vaccinating (with inactivated vaccine), household contacts or carers of immunocompromised individuals, i.e. individuals who expect to share living accommodation on most days over the winter and for whom close contact is unavoidable. Child contacts of very severely immunocompromised individuals should be given inactivated vaccine rather than the live intranasal vaccine that would normally be recommended for children age 2 to under 18 years.



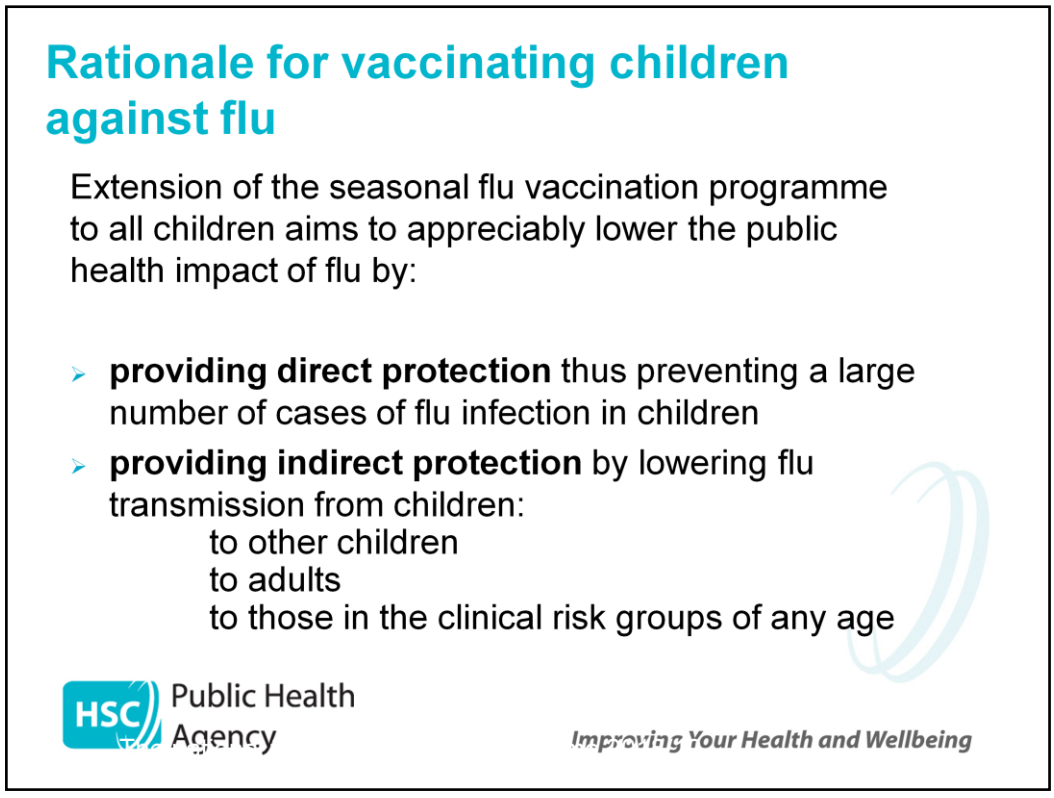
Increasing uptake of flu vaccine is important in clinical risk groups because of the increased risk of death and serious illness if people who are in these groups develop flu. In particular uptake rates in people with chronic liver and neurological disease need to be improved. Some of the highest mortality groups are associated with patients with liver and chronic Neurological disease.



All pregnant women are recommended to receive the inactivated flu vaccine irrespective of their stage of pregnancy.

There is good evidence that pregnant women are at increased risk from complications if they contract flu .In addition, there is evidence that having flu during pregnancy may be associated with premature birth and smaller birth size and weight and that flu vaccination may reduce the likelihood of prematurity and smaller infant size at birth associated with an influenza infection during pregnancy. Furthermore, a number of studies show that flu vaccination during pregnancy provides passive immunity against flu to infants in the first few months of life. A review of studies on the safety of flu vaccine in pregnancy concluded that inactivated flu vaccine can be safely and effectively administered during any trimester of pregnancy and that no study to date has demonstrated an increased risk of either maternal complications or adverse fetal outcomes associated with inactivated influenza vaccine.

The ideal time to offer flu vaccination to pregnant women is before flu starts circulating. However, even after flu is in circulation, vaccine should continue to be offered to those at risk and newly pregnant women. If a woman becomes pregnant after the usual vaccinating period of October to January, it is still worth considering offering the vaccine if flu is still circulating in the community.



In July 2012, the JCVI recommended extending the annual flu programme to include healthy children aged 2 to their seventeenth birthday in order both to lower the potentially serious impact of flu in vaccinated children and also to have a more profound effect on flu transmission. Children are the main source of transmission in the population, and extending the flu programme to include healthy children should therefore reduce the spread of infection from children to other children, to adults and to those in clinical risk groups of any age. In Northern Ireland the programme was started in pre-school children > 2 years and all primary school children. There are no plans to extend the programme into secondary schools in Northern Ireland.

Reducing flu transmission in the community will avert many cases of severe flu and flu-related deaths in older adults and people with clinical risk factors. Annual administration of flu vaccine to children is expected to substantially reduce flu-related illness, GP consultations, hospital admissions and deaths.

Health and social care workers

- frontline health and social care workers have a duty of care to protect their patients and service users from infection
- vaccination of health and social care workers protects them and reduces risk of spreading flu to their patients, service users, colleagues and family members
- evidence vaccination significantly lowers rates of flu-like illness, hospitalisation and mortality in the elderly in long-term healthcare settings
- reduces transmission of flu to vulnerable patients, some of whom may have impaired immunity and may not respond well to immunisation
- vaccination of frontline workers also helps reduce sickness absences and contributes to keeping the Health and social care services running through winter pressures

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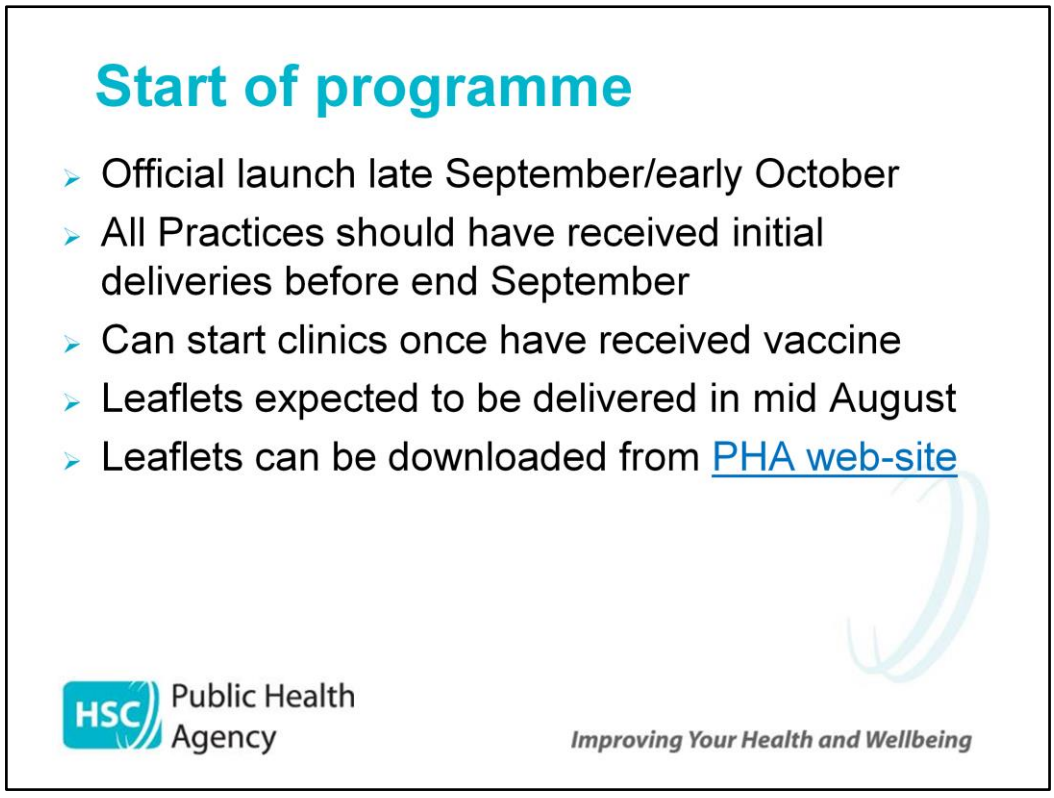
Frontline health and social care workers have a duty of care to protect their patients and service users from infection. This includes getting vaccinated against flu.

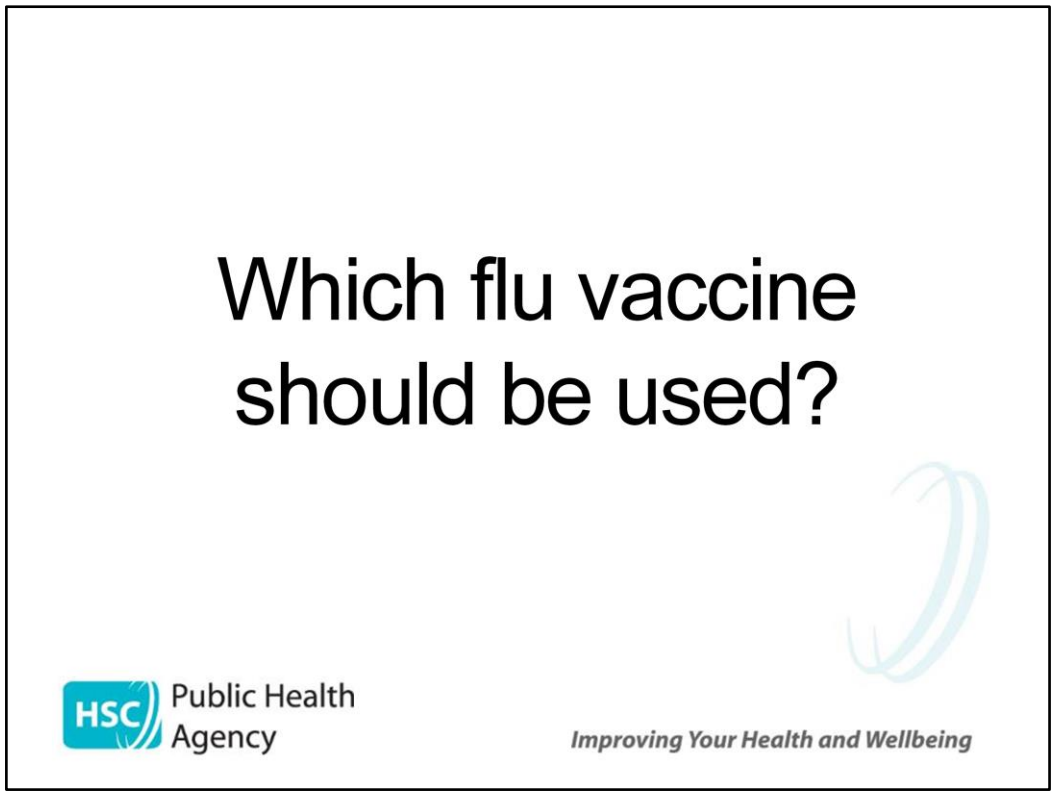
Flu outbreaks can occur in health and social care settings with both staff and their patients/service users being affected when flu is circulating in the community. It is important that health and social care workers protect themselves by having the flu vaccine, and, in doing so, they reduce the risk of spreading flu to their patients, service users, colleagues and family members.

Vaccination of healthcare workers against flu has been shown to significantly lower rates of flu-like illness, hospitalisation and mortality in the elderly in long-term healthcare settings. Vaccination of staff in acute care settings may provide similar benefits. Flu immunisation of frontline health and social staff care staff may reduce the transmission of infection to vulnerable patients, some of whom may have impaired immunity, increasing their risks of flu. These people may not respond well to immunisation.

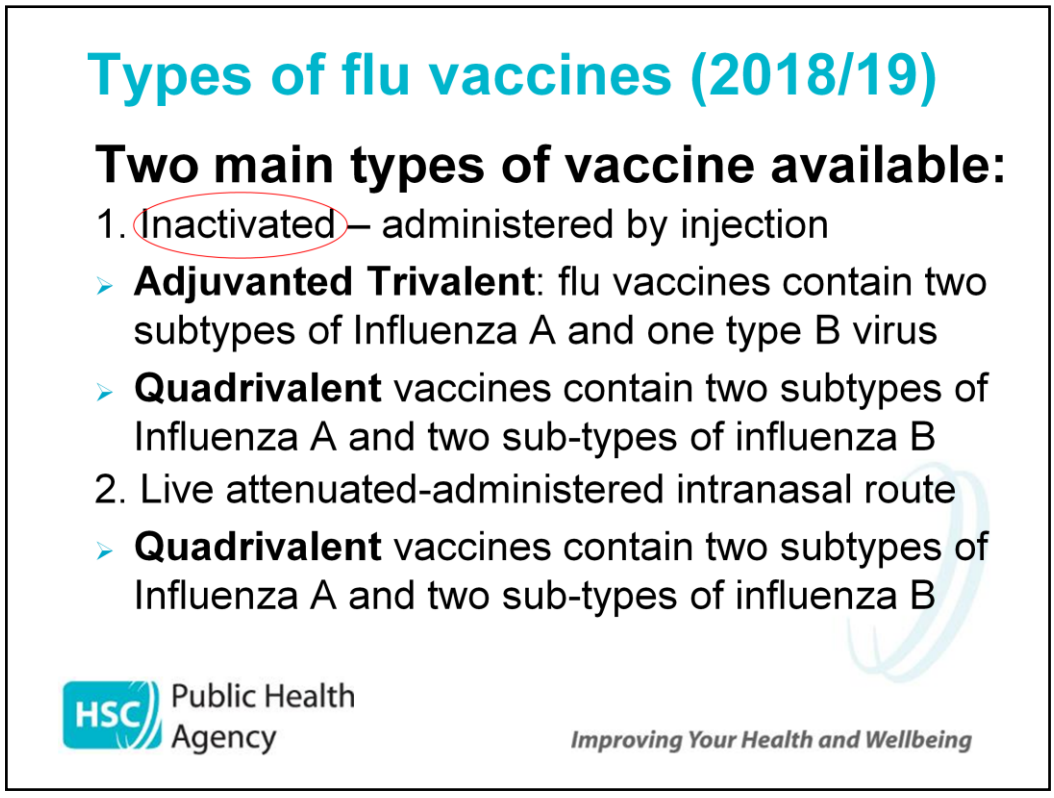
Vaccination of health and social care workers also helps reduce the level of sickness absenteeism that can jeopardise health and social care services. Flu-fighters will be working with Trusts again this year to improve uptake rates.



The official launch of the flu vaccination programme is late September / early October and there are currently no delays expected with vaccine supplies. All practice should receive initial deliveries before the end of September and vaccination. Clinics can start as soon as the vaccines have been received. Leaflets should be arriving in general practices by the last week in August and additional flu leaflets can also be downloaded from the PHA web-site http://www.publichealth.hscni.net/directorate-public-health/health-protection/immunisationvaccine-preventable-diseases.



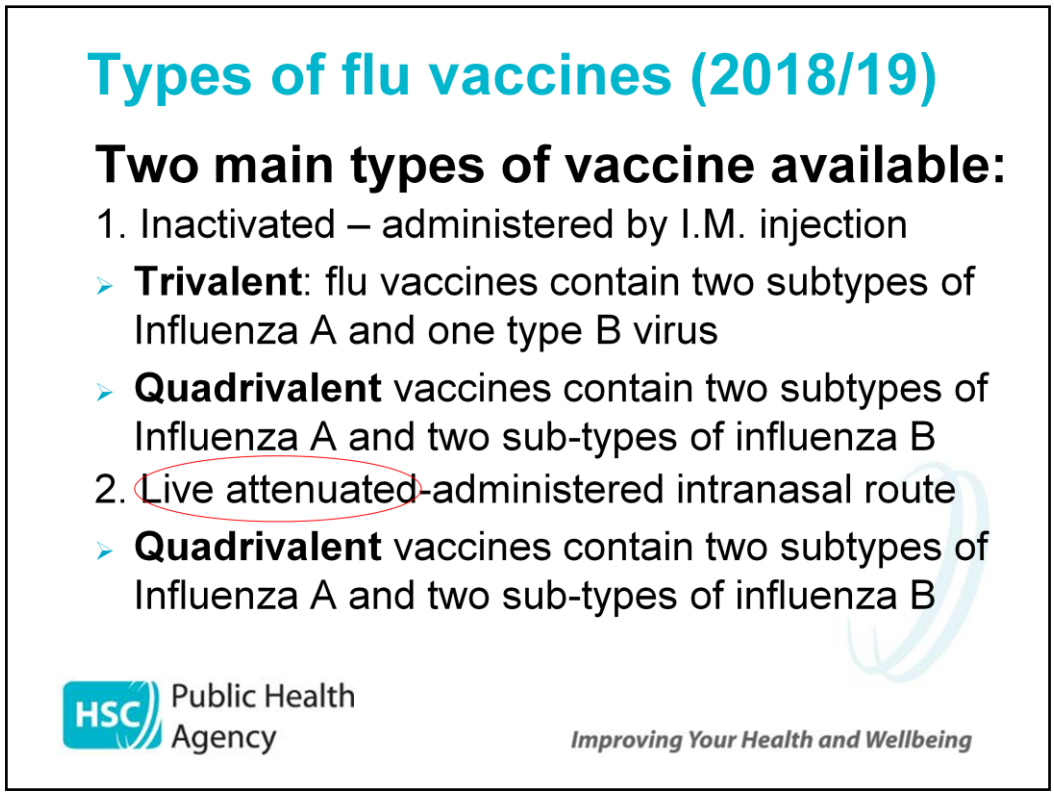
So which vaccine should you use when delivering the flu programme?



There will be two different **type**s of flu vaccines available for 2018/19 in Northern Ireland and **three** different vaccines (Fluad, Fluenz Tetra & Sanofi Pasteur Quadrivalent Inactivated Vaccine).

The first **type** of vaccine available is the **inactivated** vaccine administered by injection and there will be two injectable vaccines available to use this year:

1.The inactivated Adjuvanted trivalent vaccine contains two sub-types of influenza A and one of type B (FLUAD)
2.The inactivated Quadrivalent vaccine contains two sub-types of influenza A and two sub-types of influenza B (Sanofi Pasteur Quadrivalent Inactivated Vaccine).



The second **type** of vaccine available to use is the. live attenuated influenza vaccine (Fluenz Tetra) and it is administered intranasally. It is also a Quadrivalent vaccine and contains two sub-types of influenza
A and two sub-types of influenza B.

Flu Vaccines available (N.I.) 2018-19

Marketing Authorisation Holder	Name of Product	Vaccine Type	Admin route	Age	Suitable for Egg Allergy Patients	Suitable for latex Allergy Patients
Seqirus UK Limited;	**Fluad®** **Adjuvanted Trivalent Influenza Vaccine (aTIV)**	Surface antigen, inactivated Adjuvanted with MF59C.1	Intramuscular injection	65 years and over	No	No
Sanofi Pasteur t/a Aventis Pharma Limited	**Quadrivalent Influenza Vaccine**	Split virion, inactivated virus	Intramuscular injection	From 6 months	Yes	Yes
AstraZeneca UK Ltd	**Fluenz Tetra®**	Live Attenuated	Nasal spray	From 24 months to less than 18 years old	Yes	Yes

FLUAD is the name of the trivalent Adjuvanted inactivated vaccine recommended for use in all patients 65+ this Year. This vaccine is not suitable for patients with an egg / latex allergy.

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AstraZeneca UK Ltd	**Fluenz Tetra®**	Live Attenuated	Nasal spray	From 24 months to less than 18 years old	Yes	Yes

The Majority of patients who cannot receive **FLUAD** will be able to receive Sanofi Pasteur Quadrivalent inactivated vaccine which is now licensed for use from 6 months +. This vaccine will also be used in patients age 6 months to < 2years and age 18 to < 65 years in clinical at-risk groups.

Fluenz Tetra (the Quadrivalent live attenuated influenza vaccine), administered via the intranasal route remains the vaccine of choice for children from 2 years to < 18 years unless contra-indicated. In most cases when Fluenz Tetra is contraindicated e.g. uncontrolled asthma / immunosuppression, the patient will be able to receive the **Sanofi Pasteur Quadrivalent inactivated flu vaccine.**

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AstraZeneca UK Ltd	**Fluenz Tetra®**	Live Attenuated	Nasal spray	From 24 months to less than 18 years old	Yes	Yes

As already mentioned **Fluenz Tetra** (the Quadrivalent live attenuated influenza vaccine), administered via the Intranasal route remains the vaccine of choice for children from 2 years to < 18 years
unless contra-indicated. In most cases when **Fluenz Tetra** is contraindicated e.g. uncontrolled asthma / immunosuppression, the patient will be able to receive the **Sanofi Pasteur Quadrivalent inactivated flu vaccine**.

Inactivated Flu Vaccines

Fluad (aTIV)

Sanofi Pasteur Quadrivalent Inactivated Vaccine

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We will now cover a bit more detail about each of the vaccines available to use in this year's flu programme.

Adjuvanted Trivalent Inactivated Vaccine (aTIV)

FLUAD®

(Age 65 and over)

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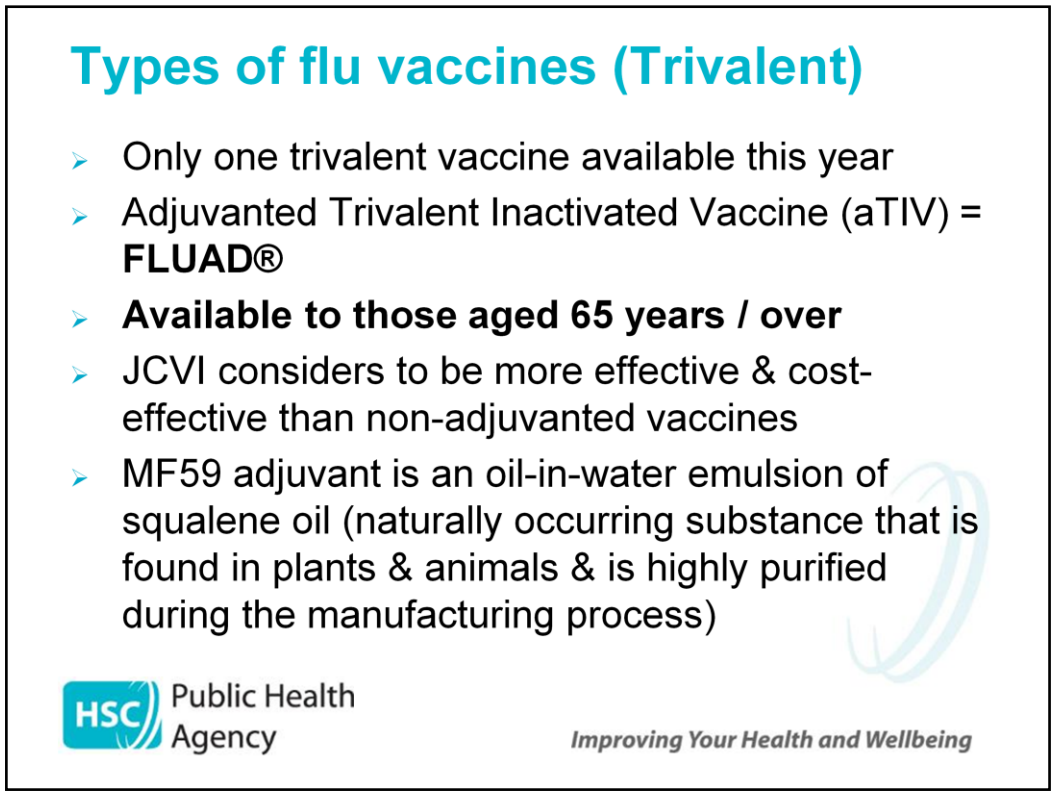
We will begin with FLUAD, the adjuvanted trivalent inactivated vaccine



Unlike previous years there will only be one trivalent vaccine available to use in Northern Ireland this year. **FLUAD** is an Adjuvanted trivalent inactivated vaccine that is available for patients aged 65+. JCVI considers **FLUAD** to be more effective and cost-effective than non-ajuvanted flu vaccines. The MF59 adjuvant is an oil-in-water emulsion of squalene oil (naturally occurring substance that is found in plants & animals & is highly purified during the manufacturing process).

As already mentioned this vaccine (**FLUAD®) is not suitable for egg / latex allergic people.** If contra-indicated for these reasons consideration should be given to offering these patients the **Sanofi Pasteur Quadrivalent Inactivated Vaccine.**

Fluad UK Packaging, PFS and needles

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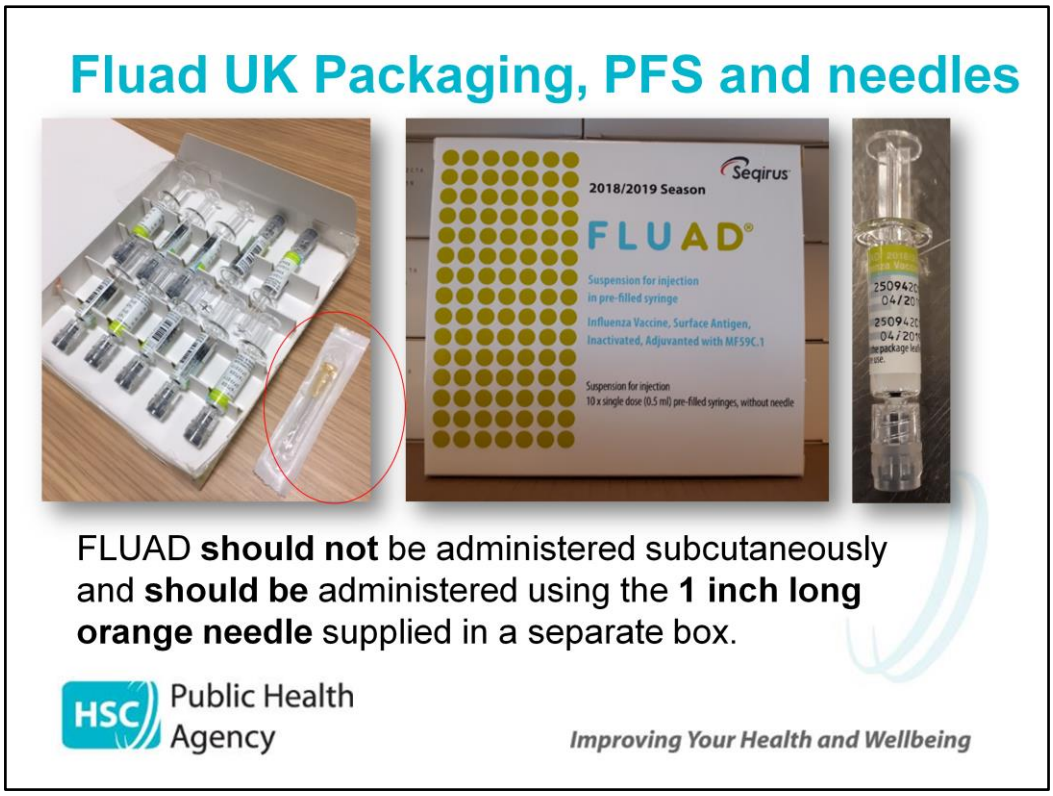
Presentation:

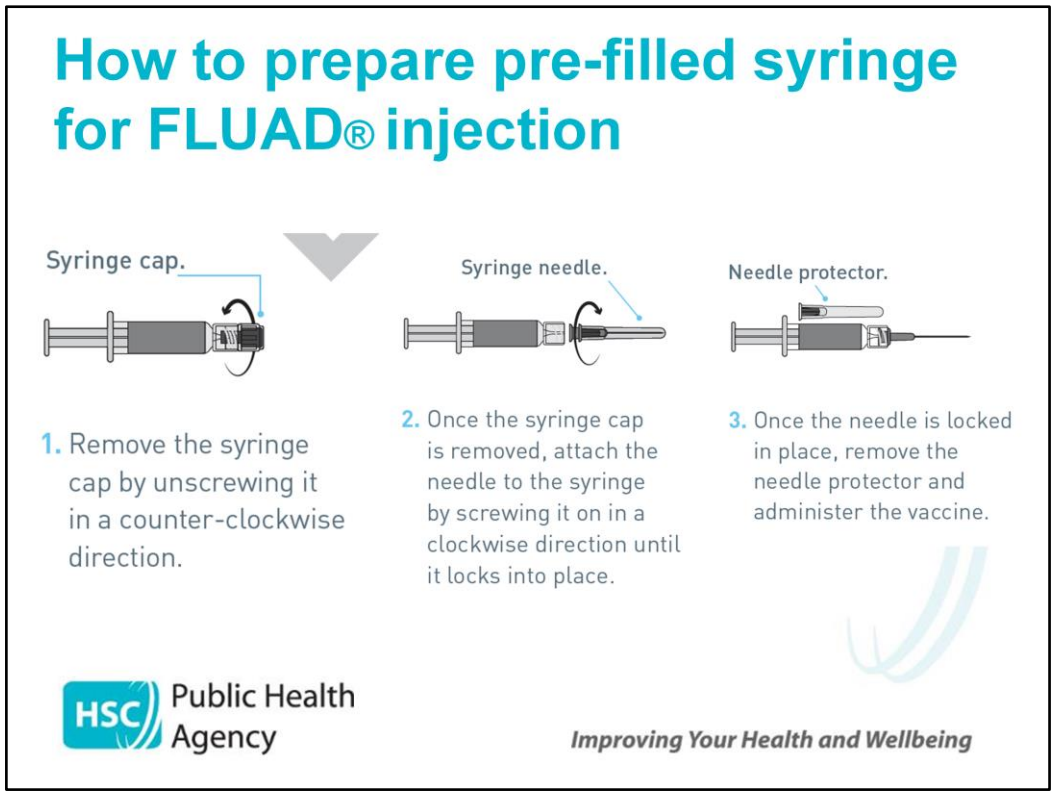
FLUAD® comes in pre-filled syringes in packs of ten. For the 2018/19 flu Season only, **FLUAD®** will be supplied in Luer Lock presentation with a separate 1-inch needle supplied in boxes.



Presentation:

It is important to note that needles supplied separately from the vaccine are 1-inch long and should not be mixed up with **25 G orange** needles that are routinely used to administer **Sub-cutaneous injections and are marked 5/8.**

Please note that FLUAD should not be administered sub-cutaneously!!



FLUAD comes in a pre-filled syringe. The syringe cap can be removed by Unscrewing it in a counter-clockwise direction.

Next attach the **1 inch 25 G orange needle** to the syringe by screwing it on in a clockwise direction until it locks in place. Once the needle is locked in place, Remove the needle protector and administer the vaccine.

Administration of FLUAD®

- Milky-white suspension
- Intramuscular Injection only
- Only one dose vaccine
- Administer single dose of 0.5ml into the deltoid muscle using a 1-inch 25G needle (orange) supplied with vaccine
- **DO NOT** administer with orange needle routinely used to administer subcutaneous injections

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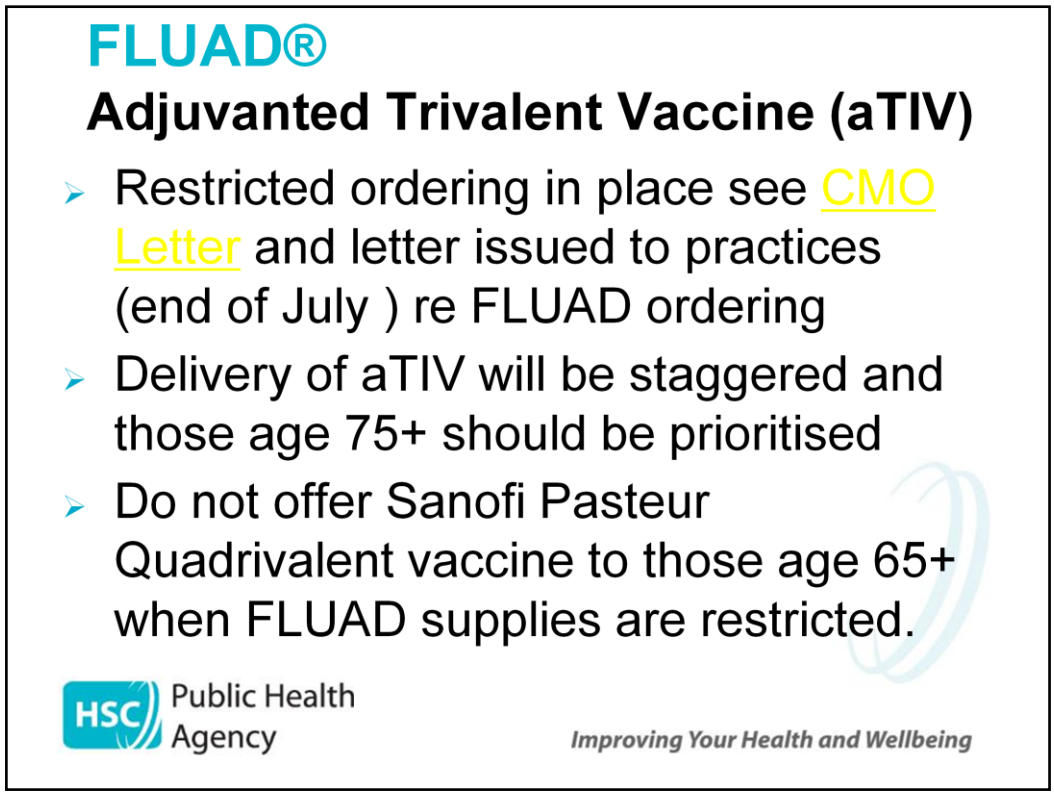
Due to the appearance of the adjuvant in FLUAD, the normal suspension of FLUAD ® is a **milky-white suspension**. FLUAD is for intramuscular injection only. Each single dose of 0.5ml must be administered into the deltoid muscle using a 25 G (orange)1-inch Needle. Higher incidence of mild post-immunisation reactions has been reported with FLUAD ® compared to non-adjuvanted influenza vaccines. This is due to the action of The MF59 adjuvant. If administering FLUAD at the same time as other vaccines e.g. PPV /Shingles it is recommended that FLUAD is given in a separate limb if possible due to the increased risk of localised reactions.

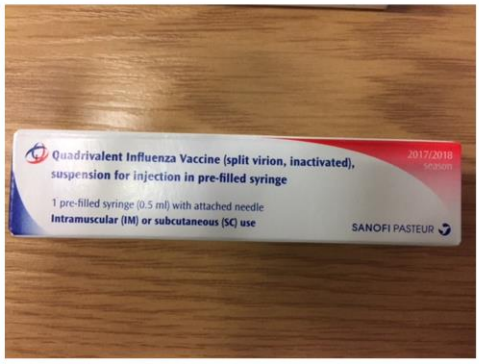


Stocks of FLUAD will be arriving in Northern Ireland in three staggered deliveries. Details of this can be found in the CMO letter and practices will also receive another letter over the summer providing more detail about their ordering quotas and suggestions for planning a practice campaign.

The JCVI have advised that the use of FLUAD (aTIV) should be a priority for those aged 75 years and over, given that the non-adjuvanted vaccine has showed no significant effectiveness in this group over recent Seasons. Those aged 65-74 years should receive FLUAD **after those** aged 75+ have been vaccinated / when restrictions have been lifted. Practices **should not** offer the Quadrivalent vaccine to those aged 65-74 when supplies of FLUAD are restricted.

Eligibility for FLUAD is determined in Northern Ireland by the age that the patient is when they attend for vaccination.

Sanofi Pasteur Quadrivalent Inactivated Vaccine



- Licensed from 6 months + (previously 3 years+)
- Children in at-risk groups age 6 months to < 2 years
- Children age 2 years to < 18 years when Fluenz Tetra is contra-indicated

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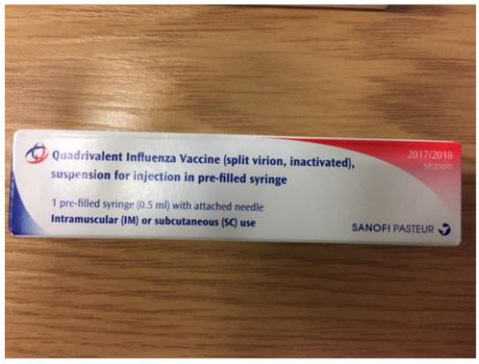
Sanofi Pasteur Quadrivalent Inactivated vaccine is now licensed for use from 6 months +. Previously the vaccine was only licensed for use in children 3 years+ and was only used in N.I. to vaccinate children in primary schools who could not receive the Fluenz Tetra (LAIV).

This year in Northern Ireland the vaccine is recommended for children in:

- clinical at-risk groups age 6 months to < 2 years and
- Children age 2 years to < 18 years when Fluenz is contra-indicated

Sanofi Pasteur Quadrivalent Inactivated Vaccine



- Adults age 18 to < 65 years
- Adults age 65+ when FLUAD® (aTIV) is contra-indicated e.g. egg allergy not did not result in anaphylaxis requiring an intensive care admission/ latex allergy

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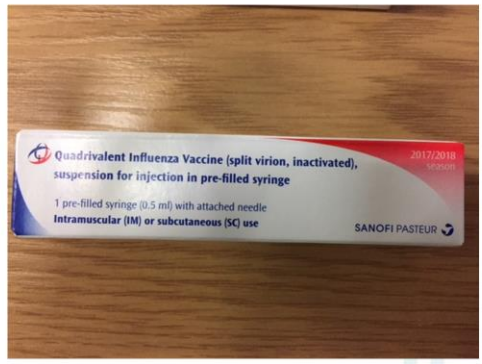
- It is also recommended for adults age 18 to < 65 years in clinical at-risk groups and
- It should be considered for use in Adults 65years+ who have a latex allergy **or** an allergy to eggs which did not result in anaphylaxis requiring an intensive care admission

Sanofi Pasteur Quadrivalent Inactivated Vaccine

- The vaccine available for delivering the flu vaccine programme for frontline healthcare workers
- Frontline healthcare workers age 65+ should attend G.P. for FLUAD® unless contra-indicated



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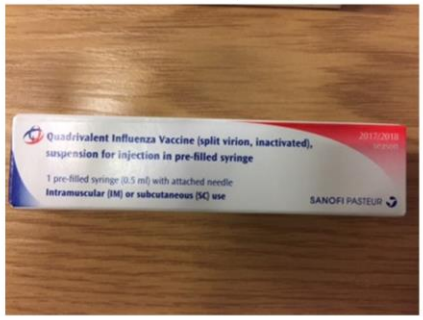
Sanofi Pasteur Quadrivalent Inactivated Vaccine is also the vaccine available for delivering the flu vaccine programme for frontline healthcare workers. If a frontline Healthcare worker is 65+ they should make an appointment attend their G.P. to receive FLUAD, unless contra-indicated. HCWs who receive their flu vaccination from their G.P. should inform occupational health so that they can be included in the vaccination uptake rates.

Sanofi Pasteur Quadrivalent Inactivated Vaccine

Supplied as suspension in pre-filled syringe containing a 0.5ml dose (colourless opalescent liquid)



- **One dose** required unless child is in a clinical risk group **and** < 9 years old **and** has not previously received a flu vaccine
- If second dose required leave at least **4 weeks** between vaccines

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Sanofi Pasteur inactivated Quadrivalent flu vaccine is supplied in a pre-filled Syringe containing 0.5 ml dose.

One dose of the vaccine is required unless the patient is a child in a clinical at-risk group **and** they are < 9 years old **and** they have not previously received a flu vaccine.

If a second vaccine is required an interval of at least 4 weeks should be left between the two vaccines.

Live attenuated influenza Vaccine (LAIV)

FLUENZ TETRA

(Age 2 to < 18)

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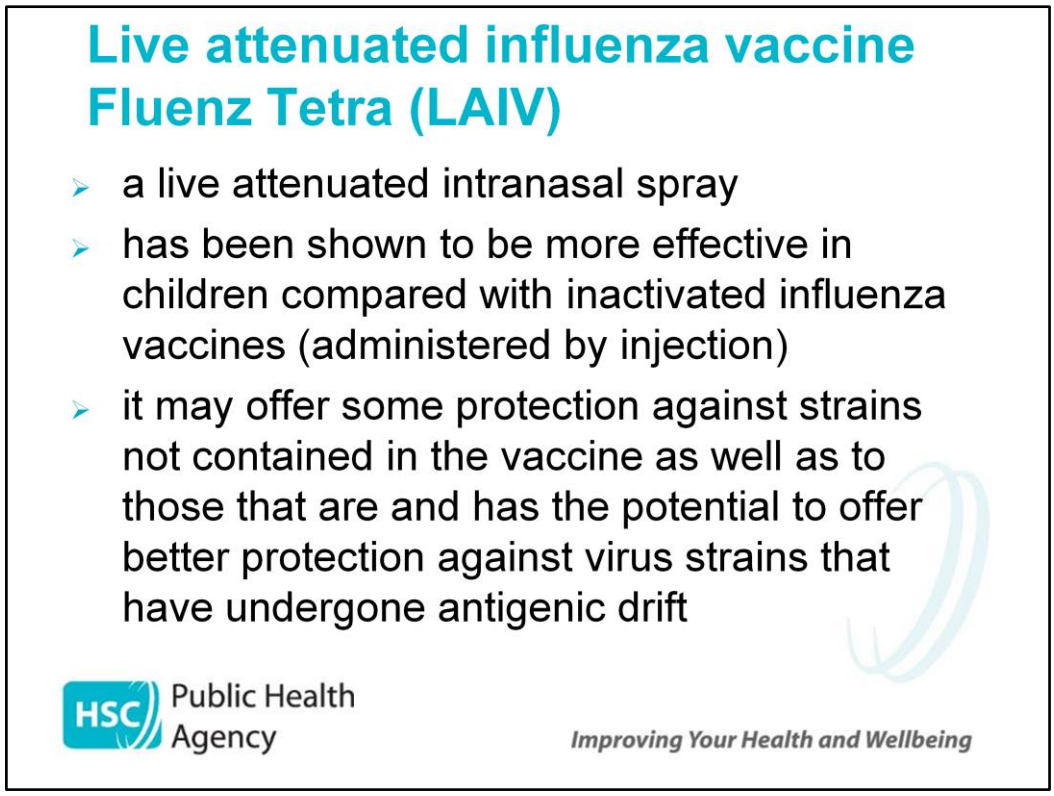
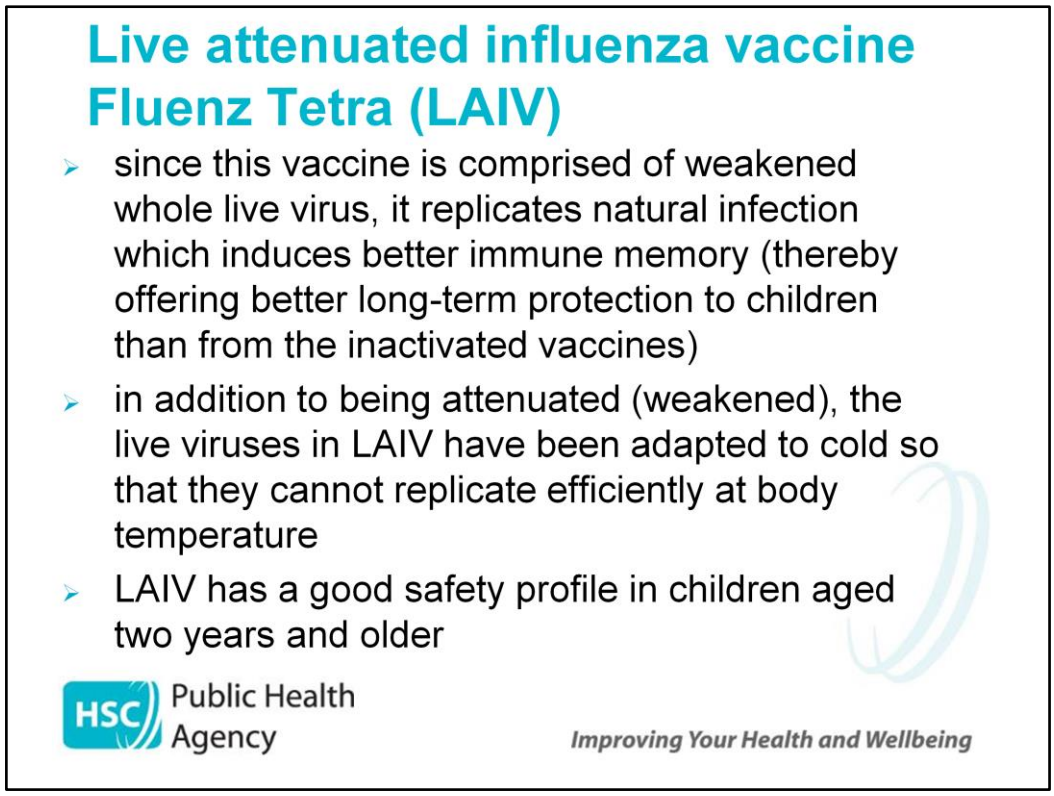
Fluenz Tetra is a live attenuated intranasal influenza vaccine. It is the recommended Flu vaccine for all children eligible for the flu vaccine > 2 years up until they reach their 18th birthday.



The Quadrivalent live attenuated intranasal influenza vaccine used in the UK is called **Fluenz Tetra®.** The majority of published literature is about **Fluenz®** (a trivalent vaccine used prior to the addition of the other B strain) but most of this literature will apply to **Fluenz Tetra®**

LAIV has been shown to be more effective in children compared with inactivated flu vaccines and it may offer some protection against strains not contained in the vaccine as well as to those that are . It has potential to offer better protection against strains that have undergone antigenic drift compared to the original virus strains in the vaccine.



Since this vaccine is comprised of weakened whole live virus, it replicates natural infection which induces better immune memory. This should mean that it also offers better long-term protection to children than they may get from the inactivated vaccines.

Fluenz Tetra contains live viruses that have been attenuated (weakened) and adapted to cold so that they cannot replicate efficiently at body temperature. The vaccine viruses replicate in the cooler nasal mucosa but not at body temperature in the lungs. This means they cannot cause clinical flu in immunocompetent children.

The live intranasal vaccine has a good safety profile in children aged two years and older and has been used for over a decade in the United States. The vaccine was extensively tested prior to it's launch in the Unites States market. Since then there has been extensive post launch surveillance in the USA, involving millions of doses in children with no evidence found of any safety concerns. It has also been used in the past five flu seasons in the UK where hundreds of thousands of children have been safely vaccinated. As with all vaccines and medicines, MHRA closely and continuously monitors the

safety of LAIV.

Live attenuated influenza Vaccine (LAIV) Fluenz Tetra

- the live intranasal flu vaccine is supplied as a nasal spray suspension in a special single use, pre-filled, nasal applicator. No reconstitution or dilution required. Each applicator contains 0.2ml (administered as 0.1 ml per nostril)

- **One dose** required unless child is in a clinical risk group **and** < 9 years old **and** has not previously received a flu vaccine
- If second dose required leave at least **4 weeks** between vaccines

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Fluenz Tetra (LAIV) is supplied in a single use prefilled nasal applicator that is ready to use. No reconstitution or dilution is required. Each applicator contains 0.2ml (that's 0.1ml administered/ nostril).
One dose is required unless the child is in a clinical risk group **and** is < 9 years old **and** has not previously received a flu vaccine. If a second dose is required at least 4 weeks intervals should be left between doses. If the child attends primary school they will be offered the first vaccine in school but there is no mop up and at-risk children should attend their G.P. for vaccination if they have missed the first dose and / require a second dose of vaccine.

Administration of Live Attenuated Influenza vaccine (LAIV)-Fluenz Tetra

It is a **live attenuated nasal vaccine and must not be injected**

do not attempt to attach a needle

LAIV can be administered at the same time as, or at any interval from other vaccines including live vaccines

patient should breathe normally – no need to actively inhale or sniff

the vaccine is rapidly absorbed so no need to repeat either half of dose if patient sneezes, blows their nose or their nose drips following administration

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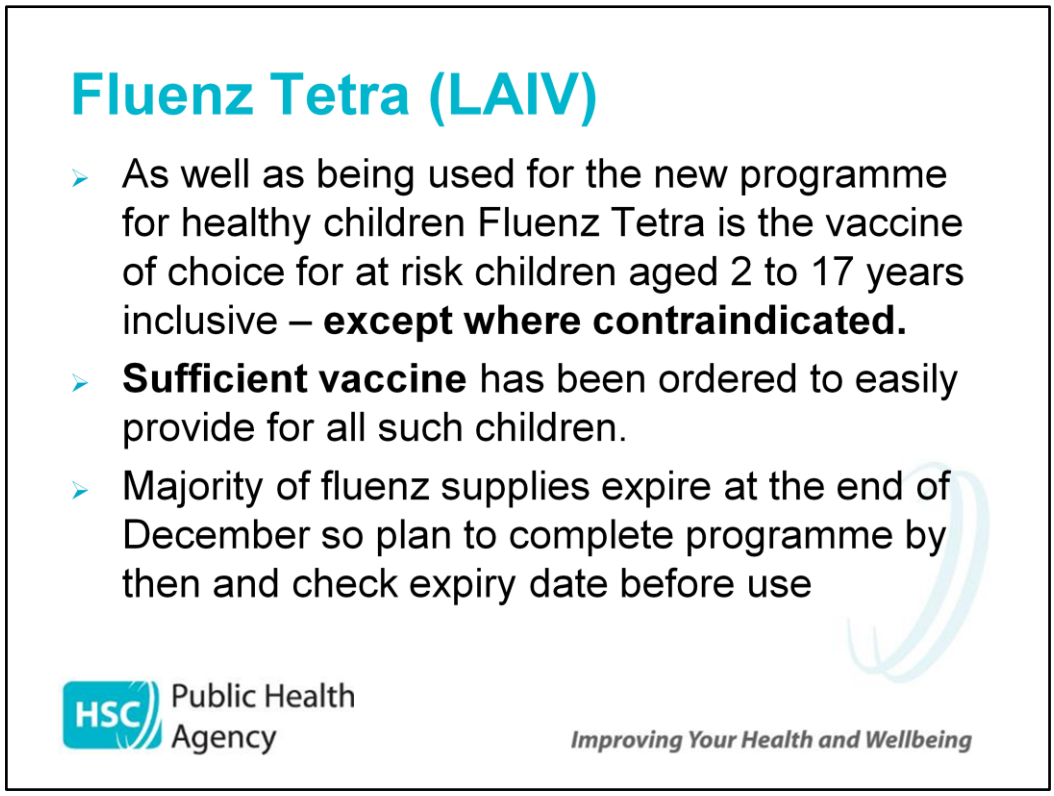
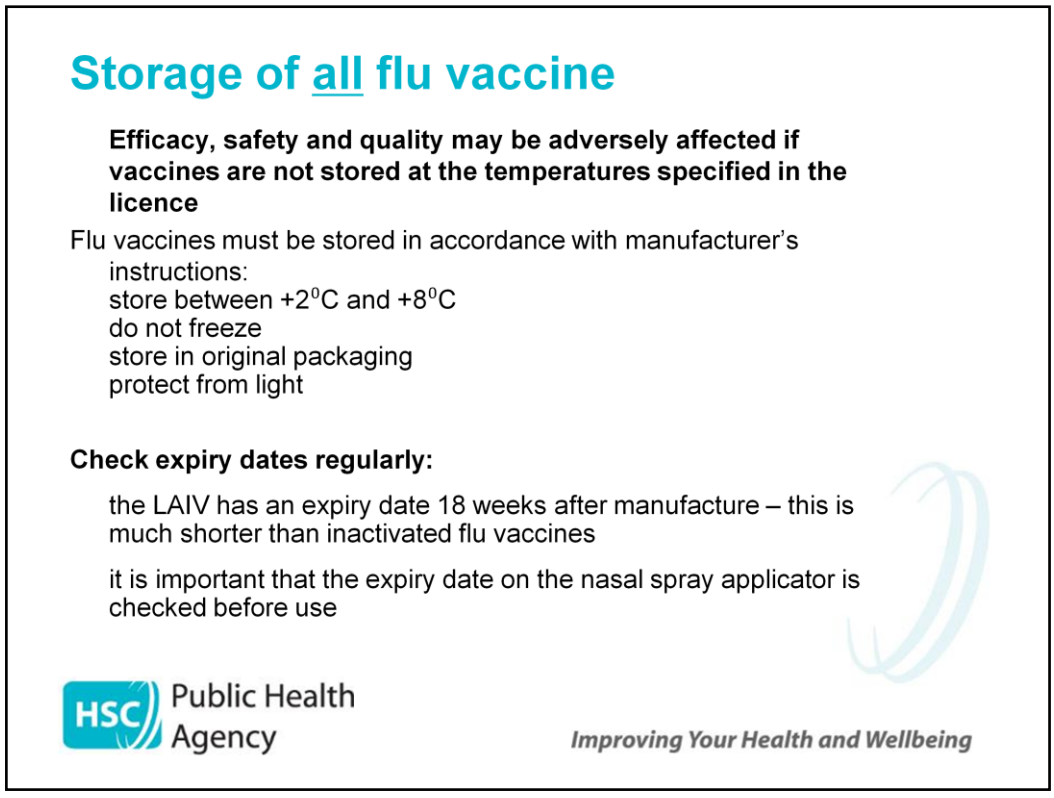
LAIV is different from other vaccines in that it is administered intranasally. The patient should breathe normally during administration. There is no need for them to actively inhale / sniff. The vaccine is rapidly absorbed and
If the patient sneezes, blows their nose / experiences nasal drips following administration,there is no need to readminister the vaccine.



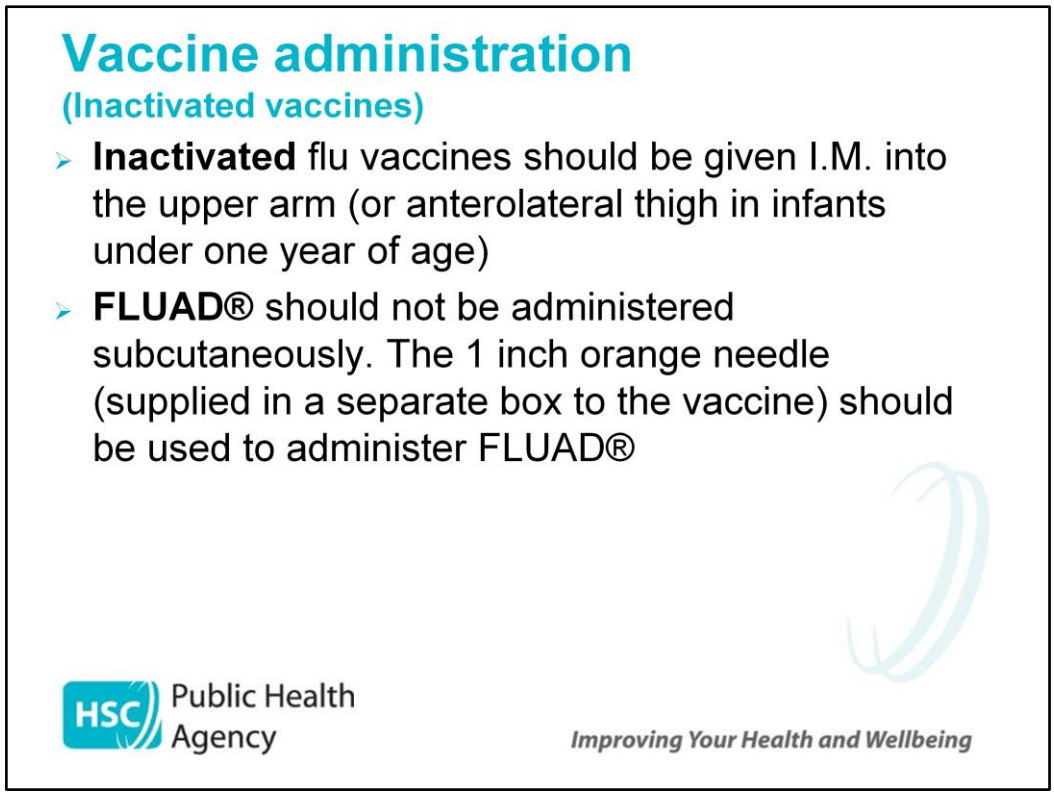
As well as being the vaccine of choice for healthy children p1-7 in the programmed delivered by the school nursing team, Fluenz Tetra is also the vaccine of choice for at-risk children age 2-17 years inclusive. It is important to note that some Fluenz Tetra stocks may expire before the end of December so expiry dates should be checked before use and an effort should be made to try and complete the programme by the end of December.



Vaccines should be stored in the original packaging at +2˚ C to +8˚ C and protected from light. All vaccines are sensitive to some extent to heat and cold. Heat speeds up the decline in potency of most vaccines, thus reducing their shelf life. Efficacy, safety and quality may be adversely affected if vaccines are not stored at the temperatures specified in the licence. Freezing may cause increased reactogenicity and loss of potency for some vaccines and can also cause hairline cracks in the container, leading to contamination of the contents.

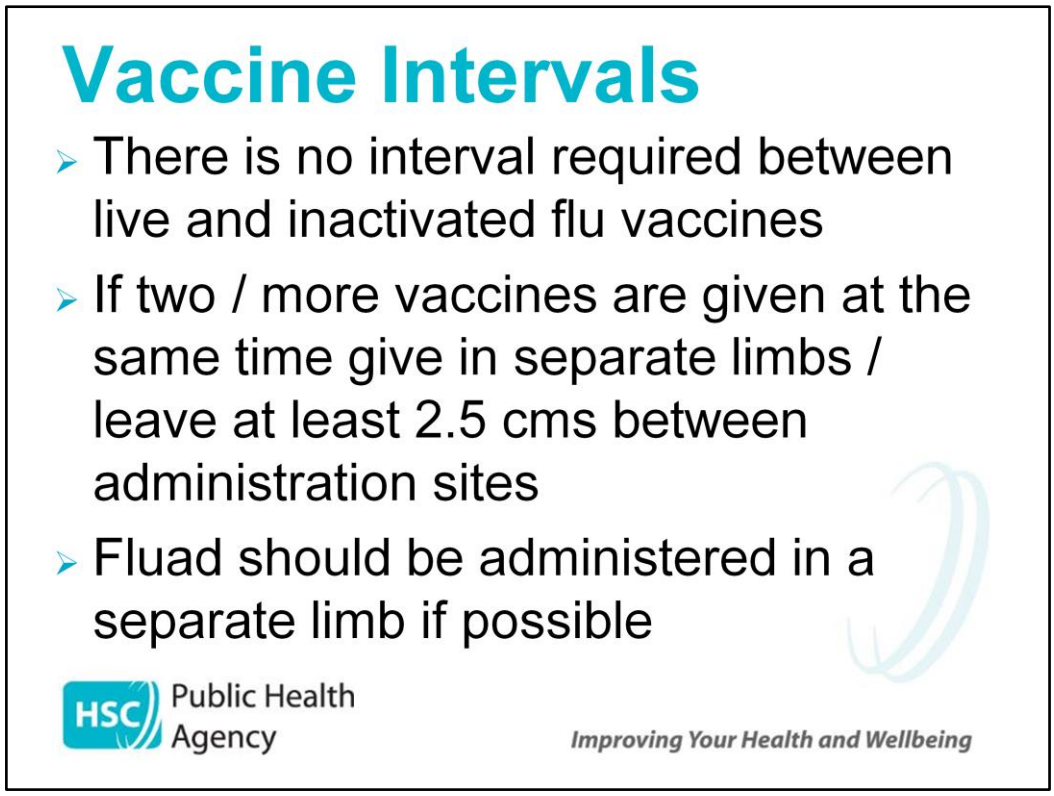
Vaccines are expensive and it is important to minimise wastage through inappropriate storage. We have had a few cold-chain failures recently where practices did not place vaccines in the Vaccine fridge on arrival to the practice, resulting in large vaccine losses and it is important to ensure that all staff responsible for handling / storing vaccines have received cold-chain training.

It is also important to check the expiry dates of flu vaccines and to rotate stock to prevent Vaccine loss. LAIV has a shelf life of 18 weeks that starts at the point of release from the manufacturer. This is a shorter shelf life than other influenza vaccines and some of this time will have passed when the vaccine reaches the place where it is to be administered. It is important that the expiry date on the nasal spray applicator is checked before use. If the expiry date has passed, arrangements should be made to have the vaccine disposed of safely.



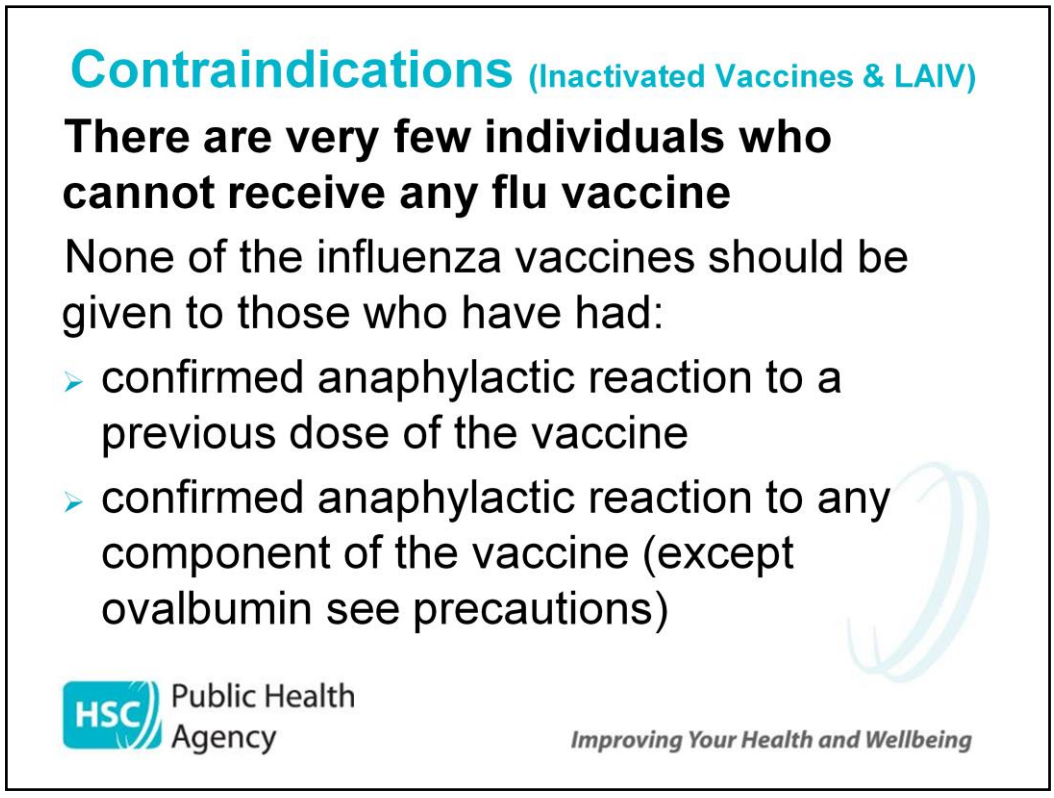
Inactivated flu vaccines should be administered into the upper arm (deltoid) in adults /anterolateral thigh in infants < 1 year.

FLUAD® should only ever be administered I.M. using the 25 G 1 inch orange needle that for this year will be supplied in a separate box from the vaccine. It is important not to administer this vaccine with an orange 5/8 length needle that is commonly used to administer s/c injections as this may result in reduced immunogenicity / exaggerated localised reaction at the injection site.



There is no interval required between inactivated and live vaccines / LAIV and any other live vaccine. If it is necessary to administer flu vaccine at the same time as other vaccines e.g. PPV / Shingles, the vaccines should be administered in separate limbs / leave at least 2.5 cms between vaccination sites.

Fluad should be administered in a separate limb if possible due to the increased risk of localised reaction. The vaccination sites should be recorded.

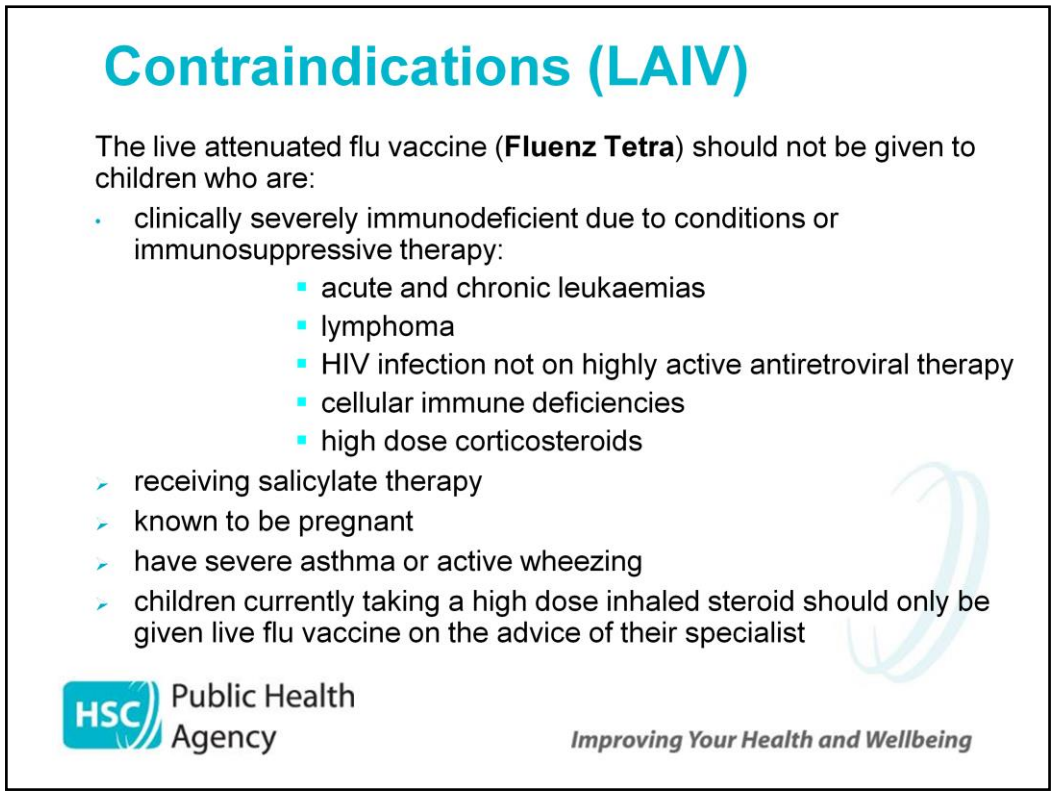


The SPCs for individual products should always be referred to when deciding which vaccine to give. There are very few individuals who cannot receive any flu vaccine.

When there is doubt, appropriate advice should be sought promptly from the health protection duty-room or the patient's consultant ,so that the period the individual is left unvaccinated is minimised. For children aged 2 years up to their 18th birthday, where live flu vaccine cannot be given, it is likely that the Quadrivalent inactivated vaccine could be given instead. For patients > 65 with an egg / latex allergy it is also likely that they will be able to receive the Sanofi Pasteur Quadrivalent inactivated Flu vaccine.

None of the influenza vaccines should be given to those who have had:

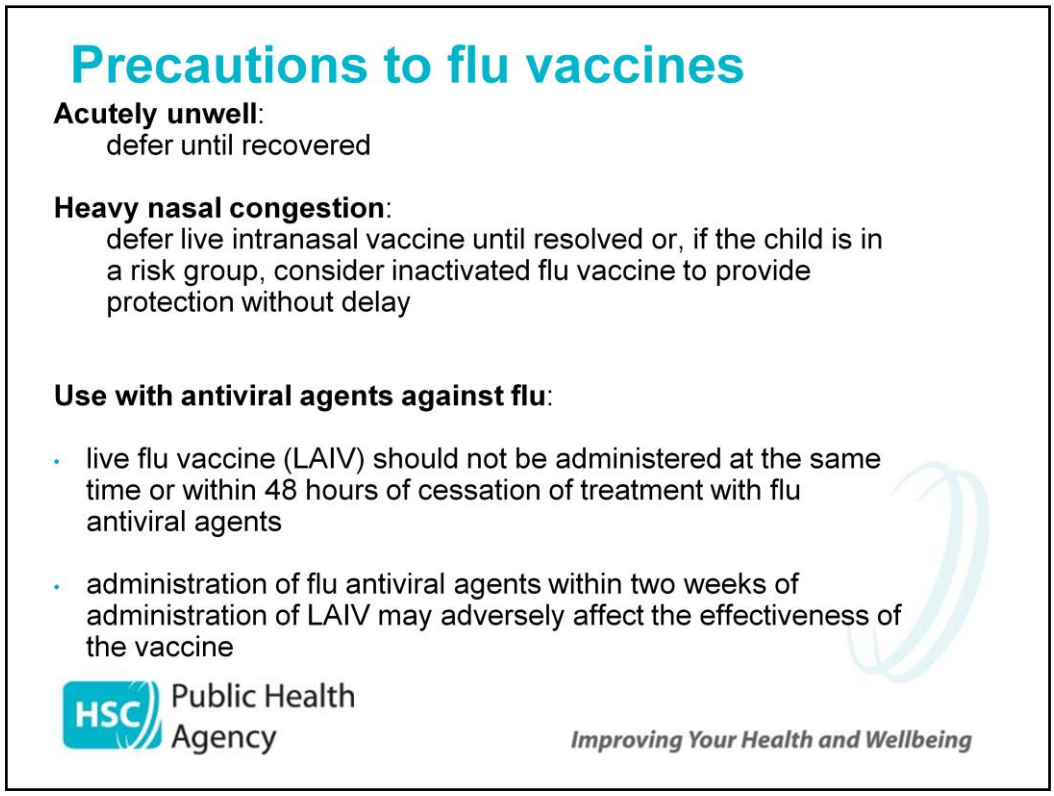
- **confirmed anaphylactic reaction to a previous dose of the vaccine**
- **confirmed anaphylactic reaction to any component of the vaccine (except ovalbumin see precautions)**



Fluenz Tetra is a live vaccine and **should not** be given to children or adolescents who are clinically severely immunodeficient due to conditions or immunosuppressive therapy such as: acute and chronic leukaemias; lymphoma; HIV infection not on highly active antiretroviral therapy (HAART); cellular immune deficiencies; and high dose corticosteroids. It is not contraindicated for use in children or adolescents with stable HIV infection receiving antiretroviral therapy; or who are receiving topical/inhaled corticosteroids or low-dose systemic corticosteroids or those receiving corticosteroids as replacement therapy, e.g. for adrenal insufficiency. Chapter 6 of the Green Book on contraindications and special precautions contains further advice on the use of live vaccines in individuals who are severely immunosuppressed. It states that the definition of "systemic high doses steroids" (and until at least three months after treatment has stopped) would include children who receive prednisolone, orally or rectally, at a daily dose (or its equivalent) of 2mg/ kg/day for at least one week, or 1mg/kg/day for one month.
Occasionally, individuals on lower doses of steroids may be immunosuppressed and at increased risk from infections. In those cases, live vaccines should be considered with caution, in discussion with a relevant specialist physician.

The live attenuated vaccine is contraindicated in children and adolescents receiving salicylate therapy (other than for topical treatment of localised conditions) because of the association of Reye's syndrome with salicylates and wild-type influenza infection as described in the SPC for Fluenz Tetra®.

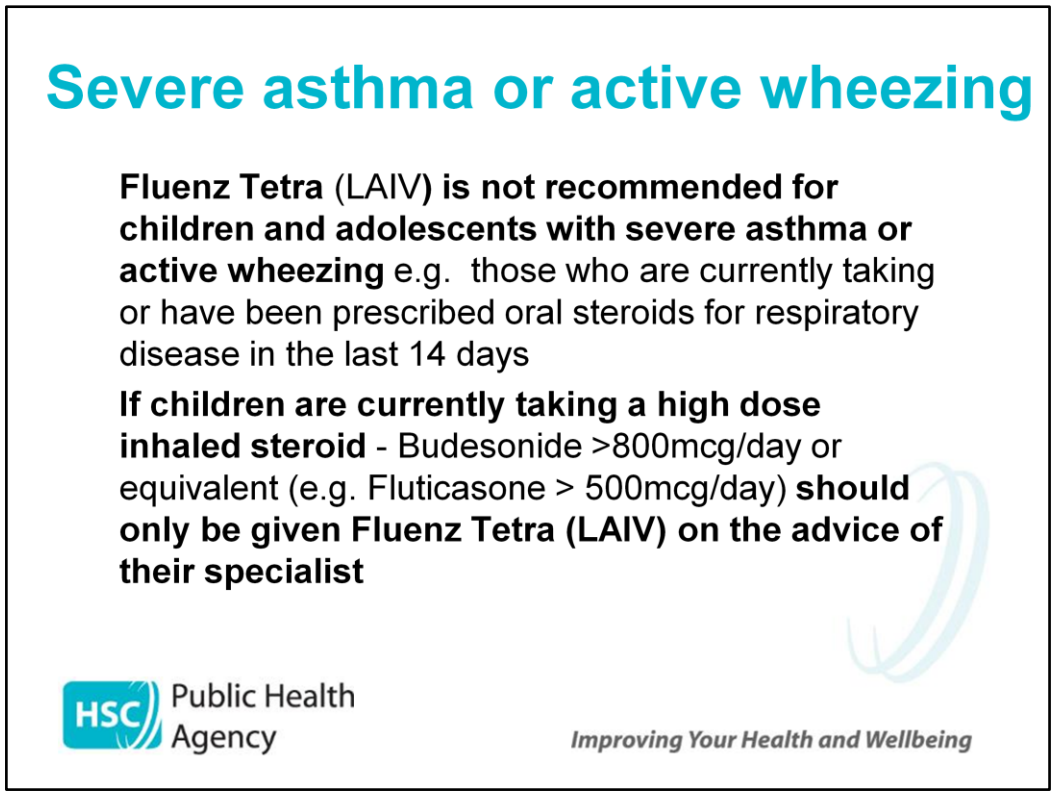
Safety data for the live attenuated flu vaccine (Fluenz Tetra®) when given in pregnancy is limited. While there is no evidence of risk with live attenuated flu vaccine, inactivated flu vaccines are preferred for those who are pregnant. There is no need, however, to specifically test eligible girls for pregnancy or to advise avoidance of pregnancy in those who have been recently vaccinated.



Minor illnesses without fever of systemic upset are not valid reasons to postpone vaccination. If the individual is acutely unwell, immunisation may be postponed until they have recovered. This is to avoid confusing the differential diagnosis of acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine.

There is no data on the effectiveness of LAIV when given to children with a heavily blocked or runny nose attributable to infection or an allergy. However as heavy nasal congestion might impede delivery of the vaccine to the nasopharyngeal mucosa, deferral of administration until nasal congestion has resolved should be considered or an appropriate alternative influenza vaccine that is administered by injection should be considered.

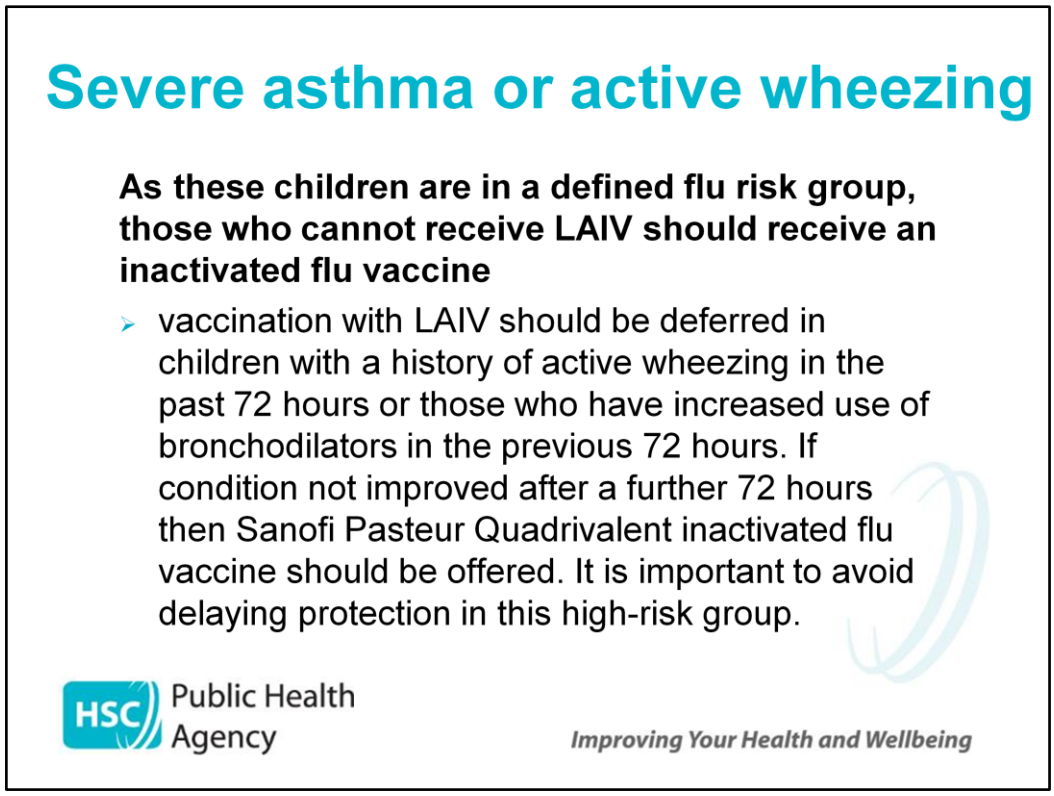
There is a potential for influenza antiviral agents to lower the effectiveness of the live attenuated influenza vaccine. Administration of influenza antiviral agents within two weeks of administration of LAIV may adversely affect the effectiveness of the vaccine.



Fluenz Tetra (LAIV) is not recommended for children and adolescents with severe asthma / active wheezing e.g. those who are currently taking / have been prescribed oral steroids for respiratory disease within the past 14 days. There is limited safety data on children currently taking a high dose of inhaled steroid. If children are currently receiving a high dose of inhaled steroid, Fluenz Tetra (LAIV) should only be administered on the advice of their specialist.

It is important to note that these children are in a clinical risk group and that those who cannot receive LAIV, should be offered an appropriate inactivated flu vaccine.

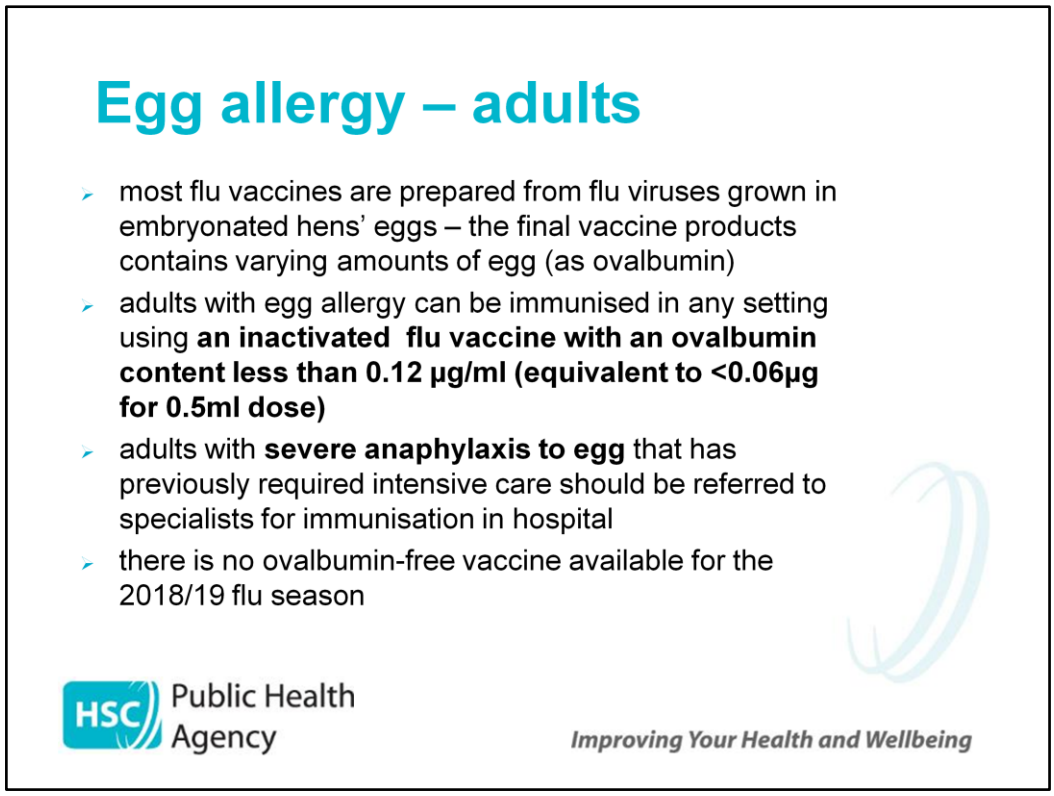
Vaccination of children with LAIV should be deferred if they have a history of an active wheeze in the past 72 hours / increased use of bronchodilators in the previous 72 hours.



It is important to note that these children are in a clinical risk group and that those who cannot receive LAIV, should be offered an appropriate inactivated flu vaccine.

Vaccination of children with LAIV should be deferred if they have a history of an active wheeze in the past 72 hours / increased use of bronchodilators in the previous 72 hours.

If condition not improved after a further 72 hours then Sanofi Pasteur Quadrivalent inactivated flu vaccine should be offered. It is important to avoid delaying protection in this high-risk group.



Most flu vaccines are prepared from embryonated hen's eggs and the final product contains varying amounts of egg protein known as ovalbumin. Adults with egg allergy can be immunized in any setting using an inactivated vaccine with low ovalbumin levels. If however their egg allergy resulted in anaphylaxis that required an intensive care admission, they should be referred to specialists for immunisation in hospital.
There **will not be an egg-free flu vaccine** available for the incoming flu season. FLUAD ® should not be administered to patients who have an egg allergy.

If an adult does not have a severe anaphylaxis to egg they may be able to receive Sanofi Pasteur Quadrivalent Inactivated Influenza Vaccine.

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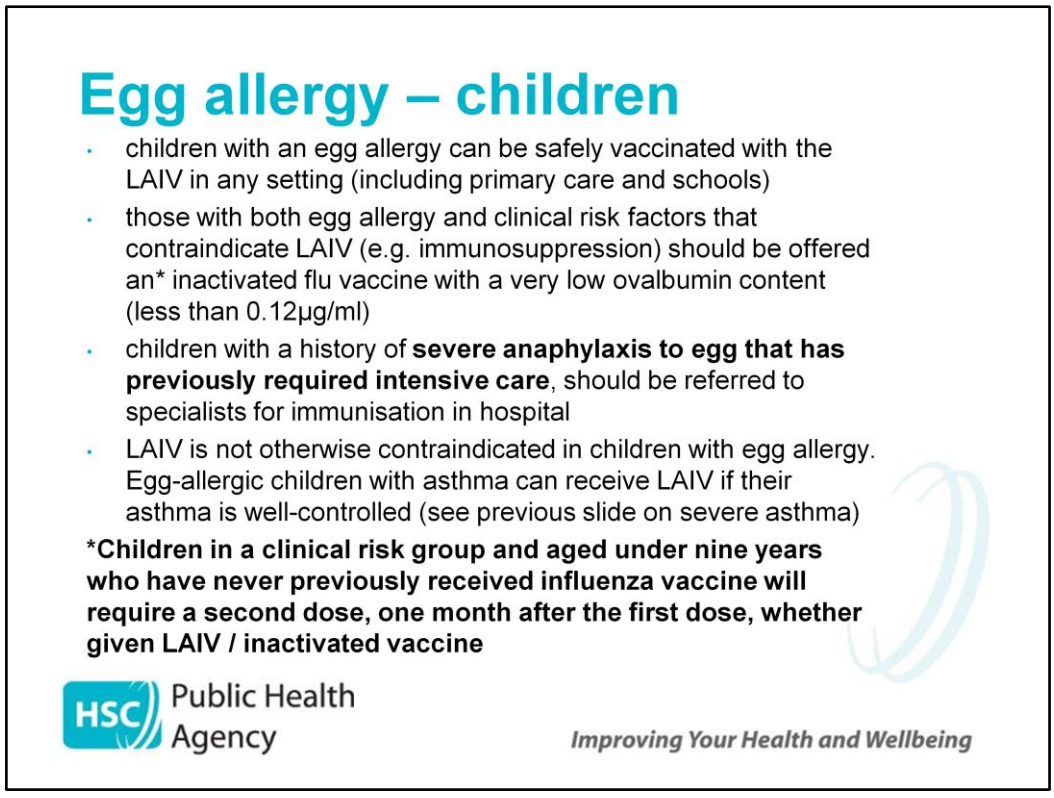


Children

JCVI has advised that, except for those with severe anaphylaxis to egg which has previously required intensive care, children with an egg allergy can be safely vaccinated with Fluenz Tetra (LAIV) in any setting (including primary care and schools); those with clinical risk factors that contraindicate Fluenz tetra(LAIV) should be offered an inactivated influenza vaccine with a very low ovalbumin content (less than 0.12µg/ml) e.g. Sanofi Pasteur Quadrivalent Inactivated Influenza vaccine.

Children with a history of severe anaphylaxis to egg which has previously required an intensive care admission, should be referred to specialists for immunisation in hospital. Fluenz tetra (LAIV) is not otherwise contraindicated in children with egg allergy. Egg-allergic children with asthma can receive LAIV if their asthma is well-controlled (see previous slide on severe asthma).

Children in a clinical risk group **and** aged under nine years who have not been previously vaccinated against flu will require a second dose whether given LAIV or inactivated vaccine.

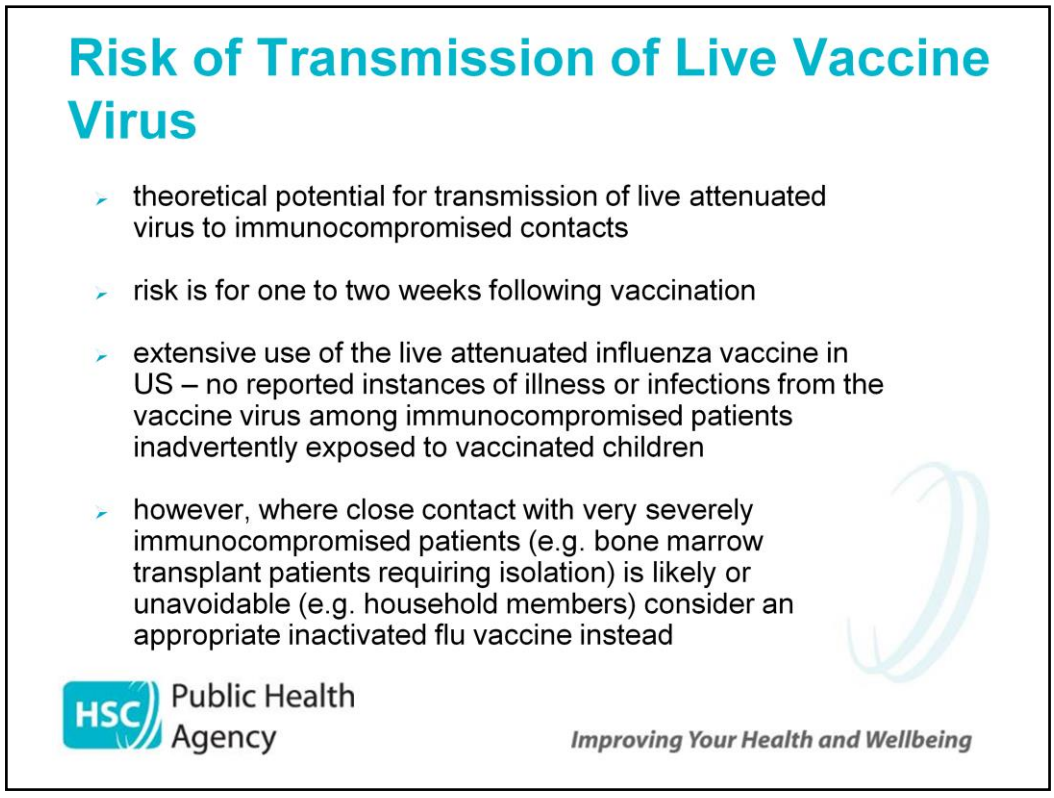
Flu vaccines with low ovalbumin content

The following vaccines, available for the 2018/19 flu season, have a very low ovalbumin content (<0.12µg/ml – equivalent to <0.06µg for a 0.5ml dose) and may be used safely in individuals with egg allergy

Supplier	Name of product	Vaccine type	Age indication
AstraZeneca UK Ltd	Fluenz Tetra	Live attenuated, nasal (quadrivalent)	From 24 months to less than 18 years of age
Sanofi Pasteur Vaccines	Quadrivalent Influenza Vaccine (Split Virion, inactivated)	Split virion inactivated virus **Note: This vaccine is only available for the school delivered flu programme**	From 6 months

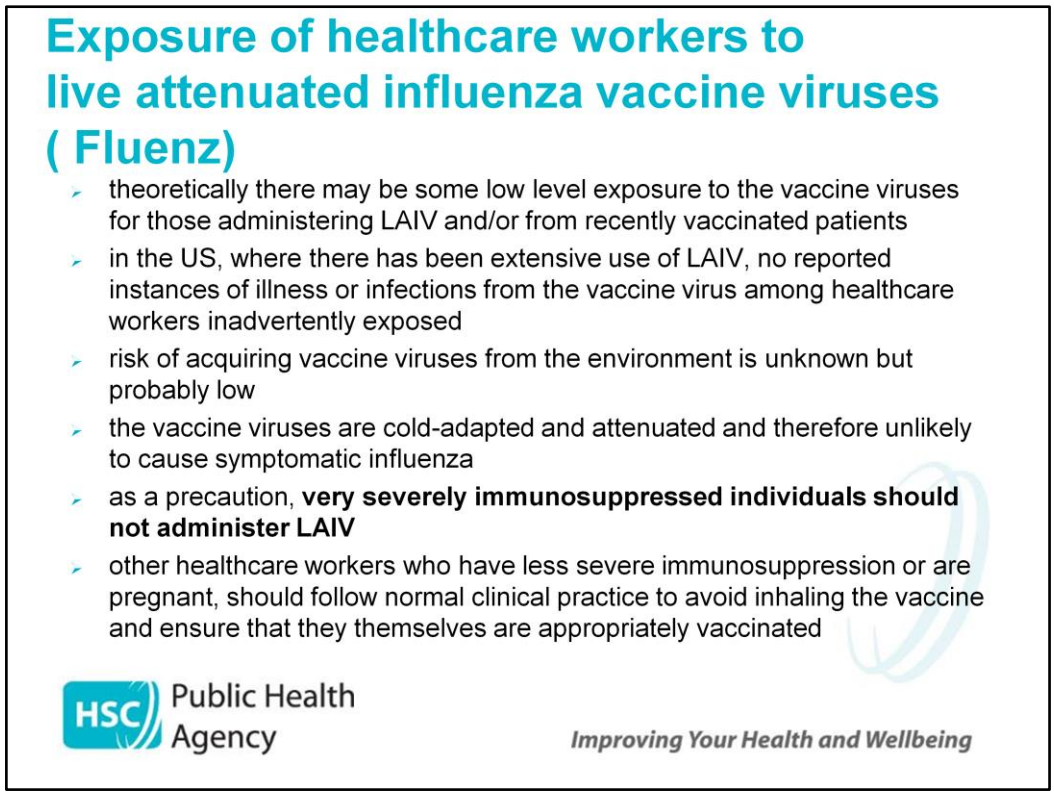
So just to recap the vaccines available for this flu season in NI with a low ovalbumin level are:

- Fluenz tetra and
- Sanofi Pasteur Quadrivalent Inactivated Influenza Vaccine



There is a theoretical potential for transmission of live attenuated influenza virus in Fluenz Tetra to immunocompromised contacts for one to two weeks following vaccination.

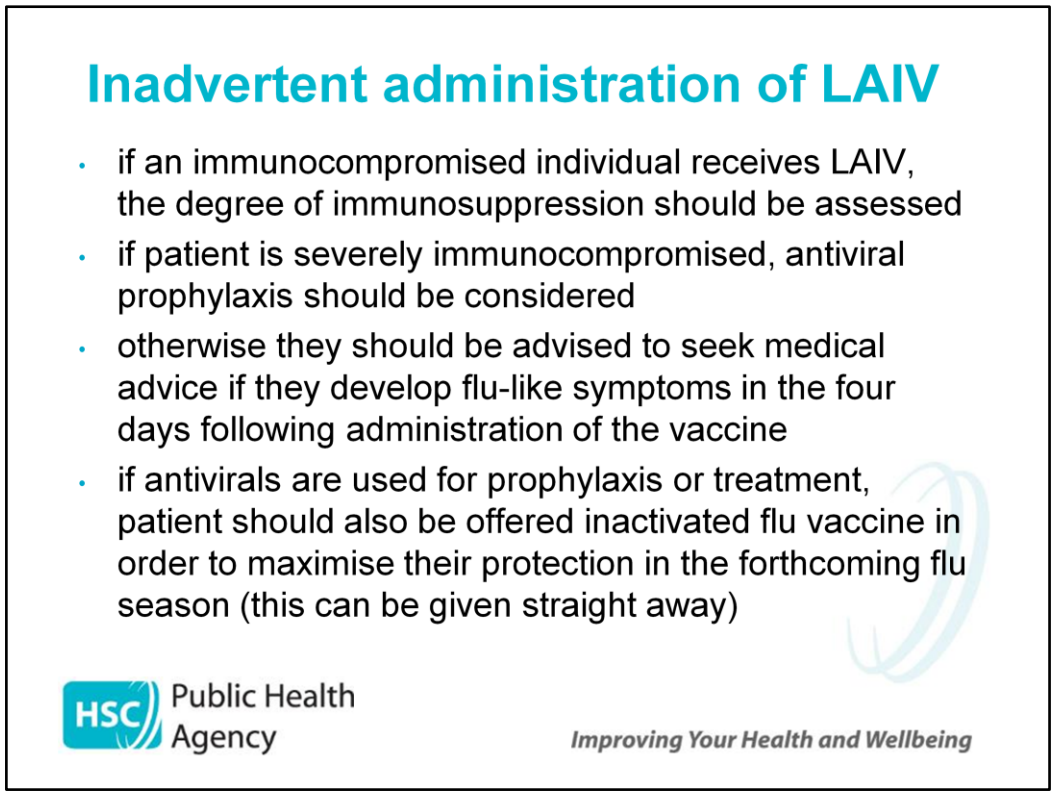
In the US, where there has been extensive use of the live attenuated influenza vaccine there have been no reported instances of illness or infections from the vaccine virus among immunocompromised patients inadvertently exposed. Where close contact with very severely immunocompromised patients (e.g. bone marrow transplant patients requiring isolation) is likely or unavoidable (for example, household members), Sanofi Pasteur Quadrivalent Inactivated Influenza Vaccine should be considered instead.



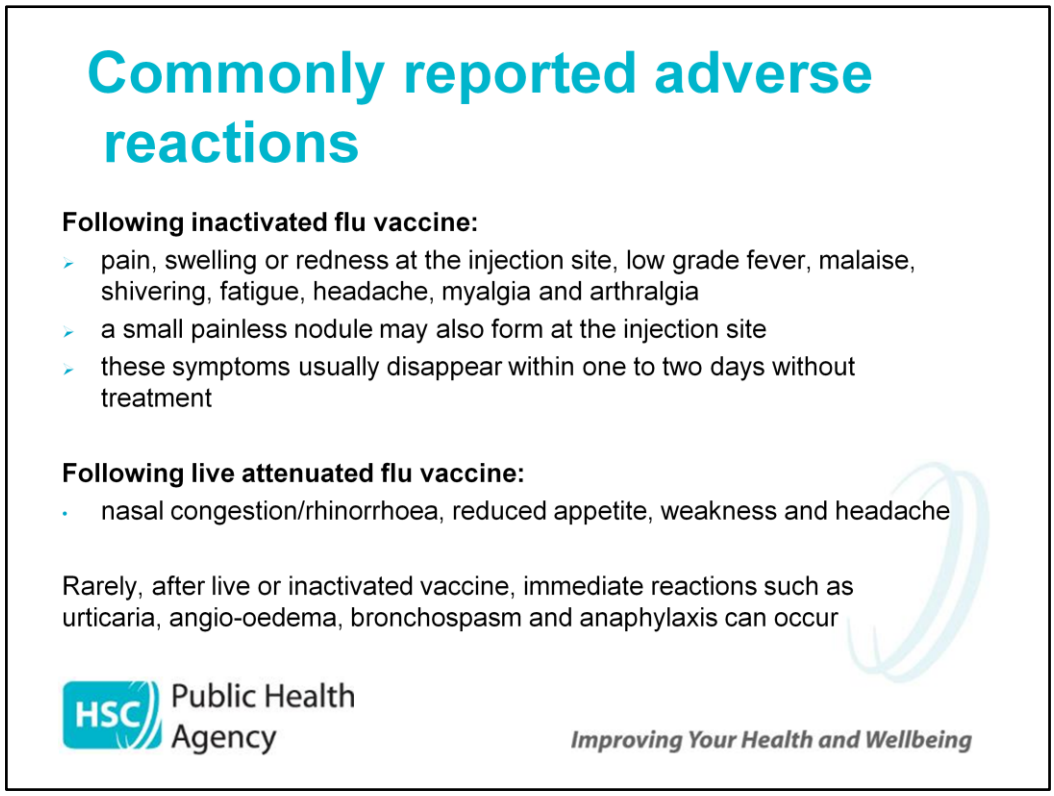
In theory, healthcare workers may have low level exposure to live attenuated influenza vaccine viruses during administration of the vaccine and/or from recently vaccinated patients. Data indicate that both children and adults vaccinated with LAIV can shed vaccine viruses after vaccination, although in lower amounts than occur typically with shedding of wild-type influenza viruses. Rarely, shed vaccine viruses can be transmitted from vaccine recipients to unvaccinated persons. However, serious illnesses have not been reported among unvaccinated persons who have been infected inadvertently with vaccine viruses.

The vaccine viruses are cold-adapted and attenuated, and are unlikely to cause symptomatic influenza. In the US, where there has been extensive use of the live attenuated influenza vaccine, no transmission of vaccine virus in healthcare settings have been reported and there have been no reported instances of illness or infections from the vaccine virus among healthcare professionals inadvertently exposed.

The Centers for Disease Control and Prevention has considered that the risk of acquiring vaccine viruses from the environment is probably low. As a precaution however, very severely immunosuppressed individuals should not administer live attenuated influenza vaccine. Other healthcare workers who have less severe immunosuppression or are pregnant, should follow normal clinical practice to avoid inhaling the vaccine and ensure that they themselves are appropriately vaccinated.



If an immunocompromised individual receives LAIV then the degree of immunosuppression should be assessed. If the patient is severely immunocompromised, antiviral prophylaxis should be considered, otherwise they should be advised to seek medical advice if they develop flu-like symptoms in the four days (the usual incubation period) following administration of the vaccine. If antivirals are used for prophylaxis or treatment, then in order to maximise their protection in the forthcoming flu season, the patient should also be offered inactivated influenza vaccine. This can be given straight away.

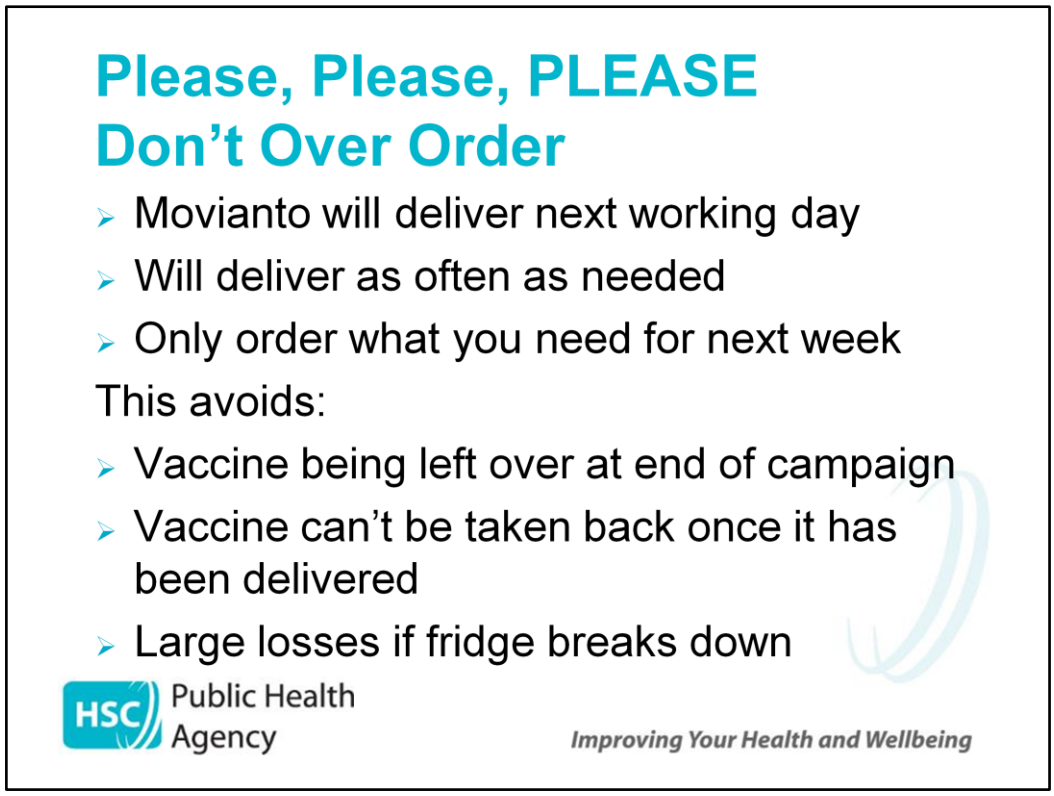


Pain, swelling or redness at the injection site, low grade fever, malaise, shivering, fatigue, headache, myalgia and arthralgia are among the commonly reported symptoms after vaccination with inactivated vaccine. A small painless nodule (induration) may also form at the injection site. These symptoms usually disappear within one to two days without treatment. Nasal congestion/rhinorrhoea, reduced appetite, weakness and headache are common adverse reaction following administration of Fluenz Tetra® (LAIV).

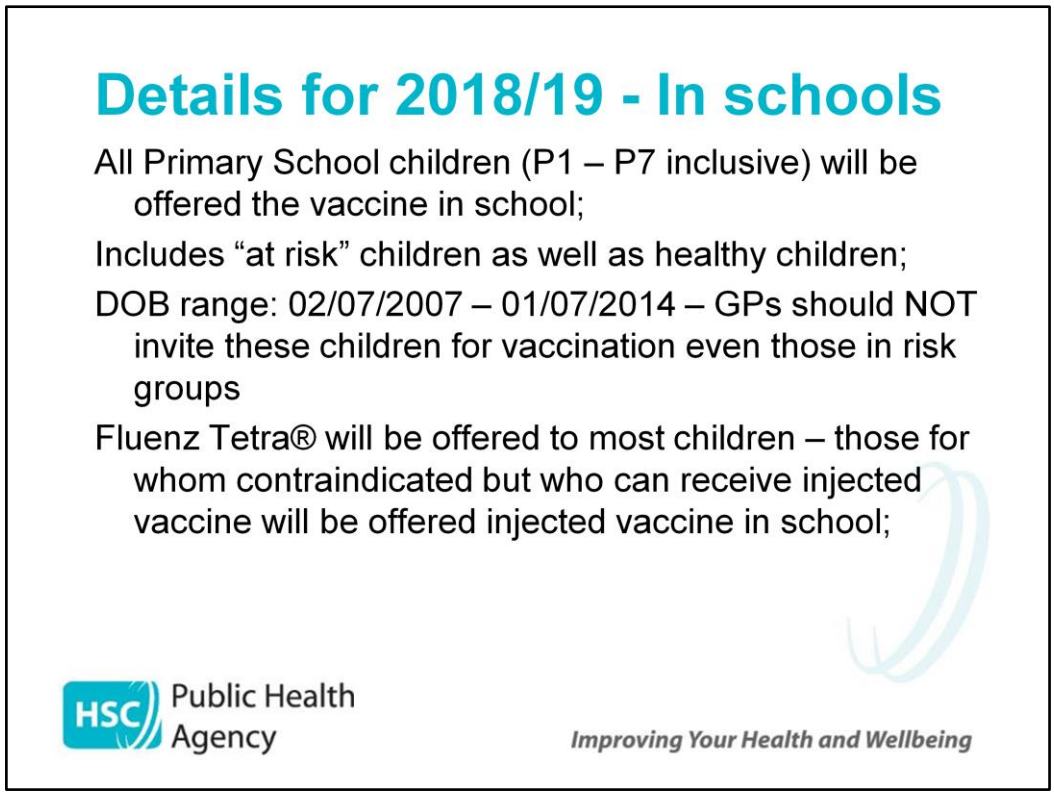
Rarely immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur.

Fluenz Tetra® and Sanofi Pasteur quadrivalent inactivated vaccine carry a black triangle symbol (▼). This is a standard symbol added to the product information of a vaccine during the earlier stages of its introduction, to encourage reporting of **all** suspected adverse reactions.

All serious suspected reactions following flu vaccines should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card scheme at http://yellowcard.mhra.gov.uk/.

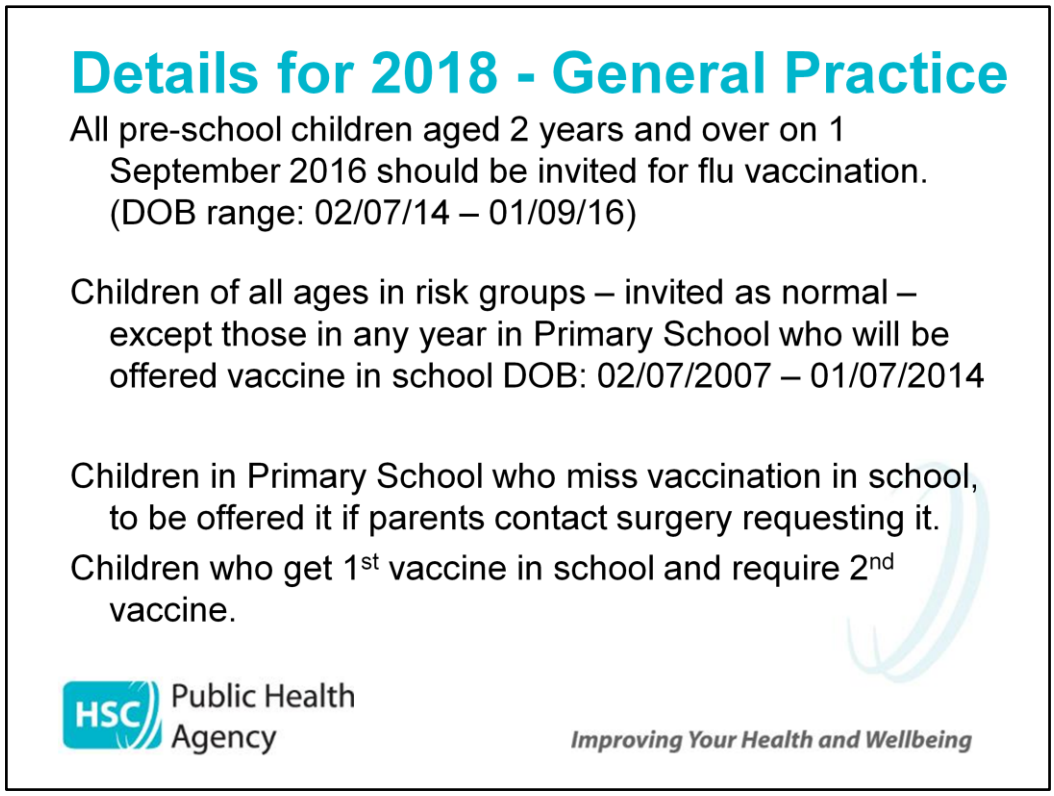


Please only order the amount of vaccines that you require and do not overstock flu Vaccine. Overstocking can result in loss of a large number of vaccines in the event of a cold-chain failure. Movianto will deliver vaccines within your quota on the next working day. Vaccines can not be returned to Movianto once they have been delivered.

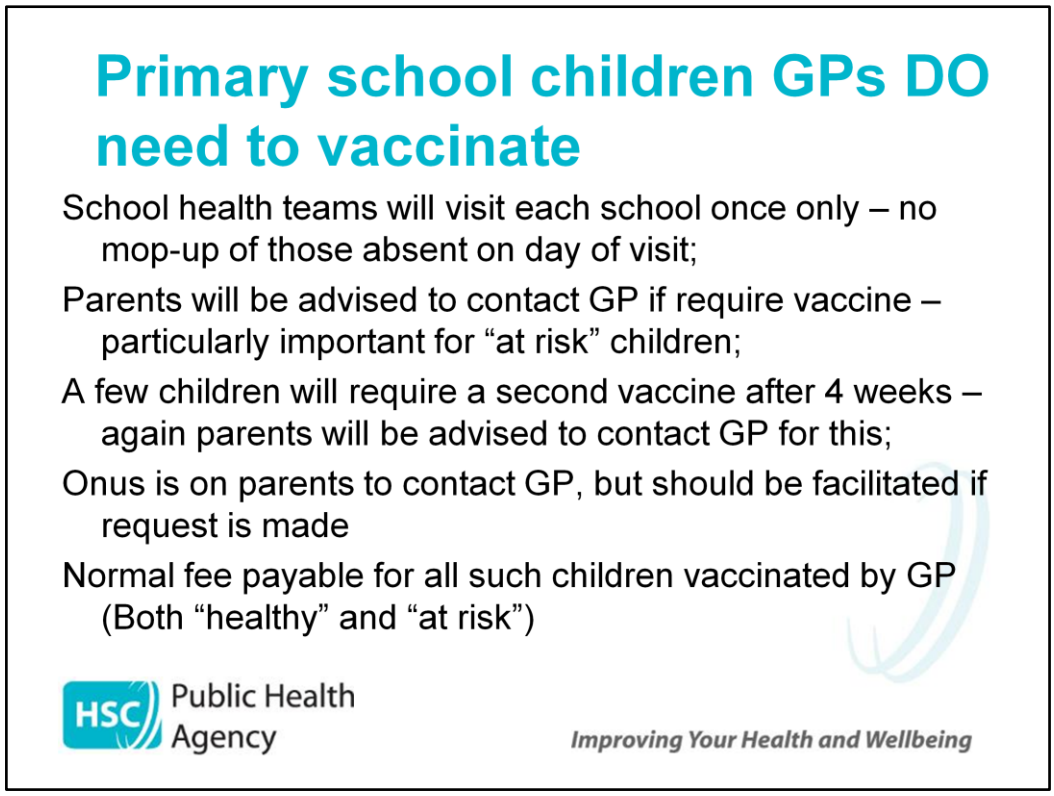


All Primary School children will be offered the vaccine in school including those in risk groups as it is thought that offering it in school will improve uptake. This includes both “at-risk” and healthy children. At-risk children will only be vaccinated by the G.P. if they have missed vaccination at school / require a second vaccine.

Even those children who cannot receive Fluenz tetra in school because of contra-indications, will be offered the alternative Sanofi Pasteur Quadrivalent Inactivated vaccine by the School nursing team.

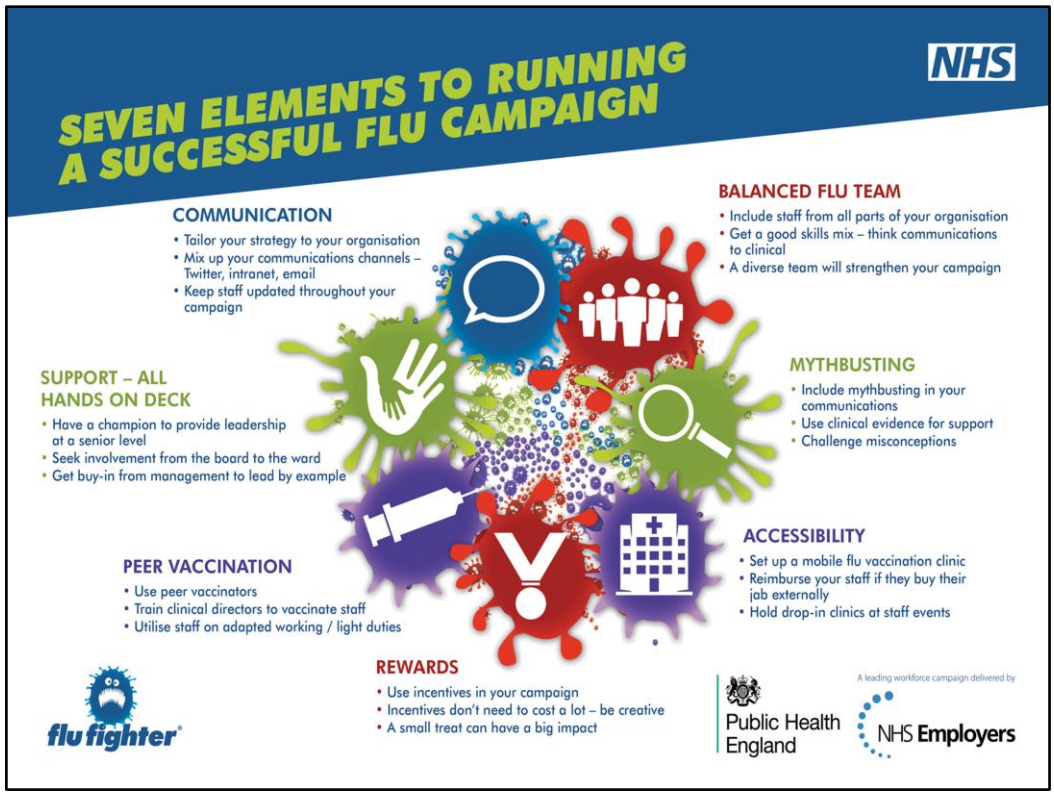


Pre-school children age 2 years and over on the 1st September should be invited by their G.P. for flu vaccination. In addition to this children in clinical at-risk groups who do not attend primary school will be invited by their G.P. for vaccination.



Due to time pressures schools will be visited once only by school health teams. Therefore if a child does not receive the vaccine on that day, because it is absent or there is no consent form etc. then they will not be vaccinated in school. Parents of such children will receive a note stating that they have not had the vaccine and that they should contact the GP surgery should they want their child to have it. It will emphasise that this is particularly important for any “at risk” children.

GPs are asked to facilitate this, the normal fee will be payable for any such children vaccinated in the GPs surgery whether “at risk” or “healthy”. If any child attending primary school requires a second vaccine 4 weeks after their first vaccine the parents will be advised to contact the child’s G.P. to arrange this.



PHA have commissioned flu-fighters again this year to assist health and social care trusts to improve their flu campaign and increase vaccine uptake rates in HCWs this year. It is really important that HCWs receive their flu vaccine. One in three people can be asymptomatic carriers of flu and HCWs receiving their flu vaccine will help to prevent patients acquiring flu.

Resources

- The Green Book: Influenza Chapter
- DOH CMO letter seasonal influenza 2018/19
- Flu patient information leaflets
- Flu healthcare worker's factsheet

HSC Public Health Agency

flu fighter

Improving Your Health and Wellbeing